A TANGLE OF BARRIERS: HOW INDIA'S INDUSTRIAL POLICY IS HURTING U.S. COMPANIES

HEARING

BEFORE THE

SUBCOMMITTEE ON COMMERCE, MANUFACTURING, AND TRADE

OF THE

COMMITTEE ON ENERGY AND COMMERCE
HOUSE OF REPRESENTATIVES

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A TANGLE OF BARRIERS: HOW INDIA'S INDUSTRIAL POLICY IS HURTING U.S. COMPANIES

THURSDAY, JUNE 27, 2013

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON COMMERCE, MANUFACTURING, AND TRADE,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 10:00 a.m., in room 2123, Rayburn House Office Building, Hon. Lee Terry (chairman of the subcommittee) presiding.

Present: Representatives Terry, Lance, Blackburn, Harper, Guthrie, Olson, Kinzinger, Johnson, Upton (ex officio), Sarbanes, McNerney, Matheson, Barrow, and Waxman (ex officio).

Staff Present: Kirby Howard, Legislative Clerk; Nick Magallanes, Policy Coordinator, CMT; Andrew Powaleny, Deputy Press Secretary; Shannon Weinberg Taylor, Counsel, CMT; Michelle Ash, Minority Chief Counsel; and Will Wallace, Minority Professional Staff Member.

OPENING STATEMENT OF HON. LEE TERRY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEBRASKA

Mr. TERRY. All right. If we could take our seats. Appreciate this. We will gavel in, and I will go ahead and start my opening.

I appreciate everyone joining us for today's hearing, which will focus on a very timely issue of how India's trade policies are affecting U.S. companies and the broader impact these policies may have on the American economy. For a long time India has been considered a close trading partner and friend of the United States. Since the 1990s, U.S. trade in goods with India has flourished into a relationship with nearly $600 billion a year. In the last decade alone, the U.S. has become India's second largest export market. And this relationship is not completely one-sided. In 2012, the U.S. exported about $20 billion in goods to India, making it our 18th largest export market, a large percentage of these exports being defense related, which is critical to maintaining strong ties with one of our closest military allies in the region.

Unfortunately, after all this progress, we are starting the see some significant and worrisome policies, particularly those related to intellectual property being adopted by the Indian Government over the last 2 years. These developments could pose a threat to the budding trade relationship.

Guided by their national manufacturing policy, India has begun engaging in a growing pattern of unfair and discriminatory trade practices which are directly harming U.S. companies in a wide variety of sectors, especially pharmaceuticals, energy technologies and information and communication technologies.

A clear example is the case of Bayer drug Nexavar. In March 2012, India issued what is called a compulsory license for this product, which meant that the Indian Government was going to allow an Indian company to receive technology owned and developed by others without any of the cost of research and development, which averages about a billion dollars for a new drug to come to market.

Bayer is not alone in its struggles with the India Government. Pfizer has had a patent for its breakthrough cancer drug Sutent revoked twice and it is currently going through another legal process.

And in April 2013, Novartis, a company I am proud to say has a large manufacturing facility just outside of my district, has a patent for Gleevec, and that has been denied.

Unfortunately, practices like these described above have clear consequences, less money spent on research, less money spent on development, and less innovation and breakthrough cures reaching dying patients all over the world, including India.

The pharmaceutical industry is not alone when it comes to American innovators being significantly harmed by India's policies. The U.S. solar panel industry has been exporting hundreds of millions of dollars' worth of U.S. made solar panels and solar cells. However, since 2010 India, as a part of its national solar mission, began requiring that these products be sourced locally, which is contrary to the established rules under the original General Agreement on Tariffs and Trade and WTO rules.

The Indian Government also has announced regulations pertaining to preferential market access for electronic goods. This mandate would set locally manufactured content requirements for procurement of several electronic goods for public and private sector entities. Concerns of GATT violations have been raised by these mandates as well.

I am hopeful that the Secretary of State Kerry can visit or revisit these issues, with Vice President Biden's visit coming up shortly thereafter. I am further hopeful that the administration will continue to raise this issue with the Indian Government at the highest levels.

Now, this committee is deeply concerned about the long-term effects these actions may have on U.S. companies, our manufacturers and our workers. It is my hope that throughout our involvement in TTIP and TPP, our representatives will work to ensure that no signatory to these treaties tolerate these type of offenses.

And I will yield back my time and recognize the gentleman from California, Mr. Waxman.

[The prepared statement of Mr. Terry follows:]

PREPARED STATEMENT OF HON. LEE TERRY

I appreciate everyone joining us for today's hearing which will focus on a very timely issue: how India's trade policies are affecting U.S. companies and the broader impact these policies may have on the American economy.

For a long time, India has been considered a close trading partner of the United States. Since the 1990s, U.S. trade in goods with India has flourished into a relationship worth nearly $60 billion a year. In the last decade alone, the U.S. has become India's second largest export market. And this relationship is not completely one-sided: in 2012 the U.S. exported about $20 billion in goods to India, making it our 18th largest export market. A large percentage of these exports being defense related, which is critical to maintaining strong ties with one our closest military allies in the region.

Unfortunately, after all this progress, we are starting to see significant and worrisome policies-particularly those related to intellectual property-being adopted by the Indian government over the past two years. These developments could pose a threat to a budding trade relationship.

Guided by their National Manufacturing Policy, India has begun engaging in a growing pattern of unfair and discriminatory trade practices which are directly harming U.S. companies in a wide variety of sectors-especially pharmaceuticals, energy technologies and information and communications technology.

A clear example is the case of Bayer's drug, NEXAVAR. In March of 2012, India issued what is called a compulsory license for this product-which meant that the Indian government was going to allow an Indian company to receive technology owned and developed by others without any of the costs of research and development—which averages over $1 billion for a new drug to come to market here in the U.S.

Bayer is not alone in its struggles with the Indian government. Pfizer has had the patent for its breakthrough cancer drug, SUTENT, revoked twice, and it's currently going through another legal appeal. And in April 2013, Novartis, a company I am proud to say has a large manufacturing facility in Nebraska, has its patent for GLIVEC, denied.

Unfortunately, practices like the ones described above have clear consequences: less money spent on research, less money spent on development, and less innovative and breakthrough cures reaching dying patients all over the world, including in India.

The pharmaceutical industry is not alone when it comes to American innovators being significantly harmed by India's discriminatory trade practices.

The U.S. solar panel industry had been exporting hundreds of millions of dollars worth of U.S. made solar panels and solar cells. However since 2010, India, as part of its "National Solar Mission," began requiring that these products be sourced locally, which is contrary to the established rules under the original General Agreement on Tariffs and Trade and WTO rules.

The Indian government has also announced regulations pertaining to Preferential Market Access for electronic goods. This mandate would set "locally manufactured" content requirements for procurement of several electronic goods for public AND private sector entities. Concerns of GATT violations have been raised by these mandates as well.

I am hopeful that Secretary Kerry's recent visit and Vice President Biden's upcoming visit will have an effect, and convey a message that resonates with the Indian government. I am further hopeful that the administration will continue to raise this issue with the Indian government at the highest levels, and at every opportunity during bilateral negotiations.

This committee is deeply concerned about the long-term effects these actions may have on U.S. companies and workers. It is my hope that throughout our involvement in the TTIP and TPP, our representatives will work to ensure that no signatory to these treaties tolerate these types of offenses.

OPENING STATEMENT OF HON. HENRY A. WAXMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. WAXMAN. Thank you, Mr. Chairman. India, the world's largest democracy, is an important ally and trading partner for the United States. It is also a market full of potential for U.S. companies, boasting the second largest population, a strong workforce, and a rising middle class.

U.S. companies are well positioned to take advantage of these opportunities if there are fair trade rules in place in India and the United States. Unfortunately, there are areas where it appears India is pursuing policies that may be inconsistent with its inter-

national trade obligations. These practices are damaging both American and Indian competitiveness in the world economy.

For example, India has given preferences to its local solar suppliers. These actions appear to violate international trade agreements and the United States is challenging them at the World Trade Organization. India also has threatened to institute local preferences for hardware and software development, which would be of great concern.

Likewise, India's treatment of the entertainment industry deserves close scrutiny. Bollywood and Hollywood are successfully collaborating on a range of projects, but India's investor restrictions lacks enforcement against piracy and the absence of strong anti-camcording laws undermine this partnership.

The issue is more complex, however, in the area of pharmaceutical patents, which is an issue that has received special attention. The 2005 WTO Agreement on Intellectual Property, known as TRIPS, gives countries clear flexibility with respect to access to medicines. The Doha Declaration adopted in 2001 allows developing countries to adopt health safeguards by compulsory licensing when necessary to protect the public health.

Without question, India is still a developing country with a third of its population living in extreme poverty. About 2.4 million people are living with HIV/AIDS. Nearly 2 million each year develop tuberculosis. Over 30 million have diabetes, and cancer cases are rising. For many, the price of medicine is the difference between life and death.

We need to be able to differentiate between pharmaceutical measures in India that genuinely advance public health and those that are unfair to patent holders. When India seeks to prevent patent abuses like evergreening that artificially delay generic competition, it may be acting within the authority granted by the Doha Declaration.

India also plays a critical role by producing one-fifth of the world's generic medicines, half of which are exported. In the battle against HIV/AIDS, Indian generics have brought the cost of HIV treatment in the developing world from $10,000 to $335 per patient per year. Brand name drug companies may not like it, but the reality is that India's robust generics market supplies affordable essential drugs both to its citizens and to developing nations around the world. If India is pressured to make its patent laws more stringent than its obligations under international trade law require, this crucial supply of medicines could be threatened.

In fact, the United States itself has benefited from these low cost generics. Our Nation purchases Indian generics through the PEPFAR Program for AIDS Relief and the Global Fund to Fight AIDS, TB, and Malaria. To date, generic procurement for PEPFAR alone has saved the U.S. Government $934 million while bringing lifesaving treatment directly to more than 5 million people.

That is why we need to recognize that while we are addressing complex and important issues today, there are nuances, not one approach to all, and I look forward to this hearing and to the testimony. I want to apologize to the witnesses. There is another hearing that is going on at the same time, and I will be back and forth,

but I will have a chance to review your testimony and hopefully get back here to ask you some really tough questions.

Thank you, Mr. Chairman.

Mr. TERRY. All right. Thank you, Mr. Ranking Member.

And at this time I recognize the vice chairman of the subcommittee, Mr. Lance, for 5 minutes, and then if you would yield to Marsha when you are finished.

OPENING STATEMENT OF HON. LEONARD LANCE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Mr. LANCE. Certainly, be happy to do so. Thank you, Mr. Chairman, and good morning to our distinguished panel. I welcome everyone to this important hearing on our important trade relationship with India. Throughout the last two decades, the United States developed a prosperous trade relationship with India that has been advantageous to both countries. Bilateral trade and goods with India has increased from fewer than $6 million in 1992 to more than $62 billion in 2012. Already, throughout the first 4 months of this year, we are trading more with India than we did in the first four months of 2012. We have become India's second largest export market and India has become our 18th largest export market.

Additionally, New Jersey's Seventh Congressional District, which I have the honor of representing, has many pharmaceutical, communications, and information technology companies benefit from trade with India. It is an emerging trade relationship that I hope can further flourish in the future.

However, in the past few years, concerns have been raised about the future of the trade relationship. These concerns center on India's recent enacting of trade barriers that discriminate against our Nation's exporters and are inconsistent with India's international agreements as well as its lack of action on intellectual property rights protection and enforcement.

In the health and telecommunications fields, these trade barriers adversely affect companies in the district I serve, in the State I serve, and in my judgment, the United States. Particularly troubling is India's actions as it relates to the United States' intellectual property laws. Last year the Indian Patent Office revoked the patent for Sutent, an anti-malaria drug manufactured by Pfizer. The Indian Government also issued a compulsory license on a Stage 3 liver and kidney cancer drug. I am concerned that the Indian Government's interest in its growing pharmaceutical market is clouding the decision-making process as it relates to intellectual property, harming United States companies.

The United States must exhibit leadership in the area of protecting IP rights. Emerging companies that adopt the Indian model of intellectual property policy making also pose a risk to United States companies. We must make it clear to all trading partners that these policies set a bad precedent and undermine our mutually beneficial trade agreements.

I look forward to examining ways that the United States and India can continue to grow strong trade and investment relationships while leveling the playing field for U.S. exporters operating

in India and protecting the intellectual property rights of our companies here at home.

And I am pleased to yield to the vice chair of the full committee, Congresswoman Blackburn.

OPENING STATEMENT OF HON. MARSHA BLACKBURN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TENNESSEE

Mrs. BLACKBURN. Thank you. And I want to welcome all of you. This is an important hearing.

When I was running the Tennessee Film Entertainment and Music Commission back in the mid-1990s, I spent a lot of time working on property rights and protecting U.S. innovators, and because of that, I really share the frustration with our job creators and our innovators that what is happening with foreign governments who are constantly trying to undermine our intellectual property and use it for their benefit and gain.

When you look at India's industrial policy, trade barriers, the rampant piracy, the tax discrimination and what appears to be an absolute disregard for our intellectual property rights, you realize that India is a country that is not willing to play by the rules right now. What is worse is that they are trying to gloss over this, and here is an example. Last week, the Indian Ambassador sent a letter to any office defending their abusive practices that are killing jobs of millions of hardworking Americans. India's principal set a disappointing example to the rest of the world. No country that calls itself a friend of the U.S. would celebrate isolationism the way that India is doing. It is a shame that India's government has gone as far as they have to threaten our bilateral relationship, U.S. trade and foreign investment.

Tennessee's IT, bio, pharmaceutical, chemical, ag, medical equipment, and other manufacturing sectors are all subject to India's punishing rules, taxes and regulations. It is no wonder we have overwhelming bipartisan agreement in Congress that India's government must reverse course or risk seriously threatening our bilateral relationship.

I have gone over my time. I yield back.

Mr. TERRY. Thank you.

At this time I am going to introduce our witnesses here today and thank all of you for being here. We will begin with Linda Menghetti Dempsey, who is with the National Association of Manufacturers, and then to Mark Elliott, Executive Vice President, Global Intellectual Property Center, U.S. Chamber. Then Roy Waldron, who is Chief Intellectual Property Officer with Pfizer, and then Jim Smirnow, who is Vice President in Trade Competitiveness at the Solar Energy Industry Association. Robert Hoffman, Mr. Hoffman is the Senior President of Government Relations for Information Technology Industry Council. Then Rohit Malpani, who came here from Geneva, and no, not Geneva, Nebraska, and he is Director of Policy and Advocacy for—why don't you say it.

Mr. MALPANI. Doctors Without Borders, or Medecins Sans Frontieres.

Mr. TERRY. All right. Well, Doctors Without Borders, if that was on there, would have been easy for me to pronounce. That is our panel, and we will start then with Linda. You are first.

STATEMENTS OF LINDA MENGHETTI DEMPSEY, VICE PRESIDENT, INTERNATIONAL ECONOMIC AFFAIRS, NATIONAL ASSOCIATION OF MANUFACTURERS; MARK ELLIOT, EXECUTIVE VICE PRESIDENT, GLOBAL INTELLECTUAL PROPERTY CENTER, U.S. CHAMBER OF COMMERCE; ROY WALDRON, CHIEF INTELLECTUAL PROPERTY OFFICER, PFIZER INC.; JOHN SMIRNOW, VICE PRESIDENT, TRADE AND COMPETITIVENESS, SOLAR ENERGY INDUSTRY ASSOCIATION; ROBERT HOFFMAN, SENIOR VICE PRESIDENT OF GOVERNMENT RELATIONS, INFORMATION TECHNOLOGY INDUSTRY COUNCIL; AND ROHIT MALPANI, DIRECTOR OF POLICY AND ADVOCACY, MEDECINS SANS FRONTIERES—ACCESS CAMPAIGN

STATEMENT OF LINDA MENGHETTI DEMPSEY

Ms. DEMPSEY. Thank you. Good morning, Chairman Terry, members of the subcommittee. I welcome the opportunity to be here today to testify on behalf of the National Association of Manufacturers, the NAM, the Nation's largest industrial trade association with 12,000 small, medium and large manufacturers in every sector throughout all 50 States.

A tangle of trade barriers is an apt description of the significant and growing challenges that manufacturers in the United States are facing in India. The U.S.-India commercial relationship is a longstanding one. Our countries were cofounders of the world trading system with the creation of the GATT in 1948, which later became the World Trade Organization, which has helped the global economy expand.

Manufacturers in the United States have long sought closer economic ties with India, particularly as India began opening its economy. Over the last decade, that relationship has grown. The United States is India's second largest export market, and we share a $60 billion relationship in manufacturing trade.

Manufacturers in the United States have faced challenges in the Indian market from very high tariffs and weak intellectual property protection and enforcement to complex and expensive regulatory processes. But over the last year-and-a-half we have seen a much broader and more damaging industrial policy being implemented in India that seeks to grow its economy at the expense of ours, to advantage Indian manufacturers while undermining manufacturers here in the United States.

For example, consistent with its national manufacturing policy issued in 2011, India has undertaken a number of actions across a range of sectors. India's preferential market access rules would impose local content requirements on the purchase of information and communications technology that could easily capture half of India's market.

In the clean energy sector, India is mandating local content and considering expanding that rule to technologies that comprise the bulk of U.S. solar exports to India. India bans imports of remanufactured medical imaging devices and other equipment while allow-

ing sales of such equipment as long as it is remanufactured in India. India has recently denied or revoked patents for nearly a dozen innovative medicines. This includes medicines that were either distributed in India free of charge or sold at a fraction of their cost. India imposes price caps on hundreds of medications but only on foreign products, not ones those that Indian researchers develop. Indian tax authorities are increasingly imposing discriminatory taxes on U.S. business. We have other critical concerns, including barriers to foreign direct investment, particularly in telecommunications as well as requirements to use local information infrastructure that inhibit cross-border data flows.

My business colleagues will go into more detail on many of these concerns, but what is clear to the NAM and our manufacturers throughout the United States is that these policies really have no other purpose than to favor India's domestic corporations, many and strategic state favored and state advantaged sectors at the expense of manufacturing and jobs here in the United States.

These actions are no way for a responsible stakeholder and rising global power to treat its second largest trading partner. They are counterproductive to India's own goals of attracting foreign investment and developing its own innovative economy. These actions are inconsistent with international norms and some of them are inconsistent with India's obligations under the GATT, now WTO, that India helped create more than 65 years ago.

Without an immediate and purposeful response, India's industrial policy could spread and be applied to other products and sectors, and it sets an unfortunate example for other countries that are sure to follow. And it makes it difficult to see how India and the United States can move effectively forward on new initiatives and a stronger relationship, such as a bilateral investment treaty that really could have a chance to help forge a stronger commercial relationship.

To demonstrate our resolve and press for real results, the NAM, GIPC, Solar Energy Group joined with 13 other trade associations last week to form the Alliance for Fair Trade With India, AFTI. Together we are asking the Obama administration to address this issue at the highest levels and to end discrimination against American exports.

We seek a level playing field and a fair shake in India. We want India to end its discriminatory industrial policy and unfair trade practices and ensure those practices are not repeated.

We understand Secretary of State Kerry raised these issues during this week's U.S.-India's strategic dialogue and we hope and expect the Indian Government will respond positively and work constructively with the manufacturing community to address and resolve these issues quickly.

A strong bilateral trade and economic relationship is essential to achieving our strategic aims with India. To have that kind of partnership we all want, India must play by the rules. Thank you.

Mr. TERRY. Well done.

[The prepared statement of Ms. Dempsey follows:]

NATIONAL ASSOCIATION OF
Manufacturers

Leading Innovation. Creating Opportunity. Pursuing Progress.

Testimony

of Linda Menghetti Dempsey
Vice President
International Economic Affairs
National Association of Manufacturers

before the House Committee on Energy and Commerce
Subcommittee on Commerce, Manufacturing and Trade

on "A Tangle of Trade Barriers: How India's Industrial Policy is Hurting U.S. Companies"

June 27, 2013

TESTIMONY OF LINDA MENGHETTI DEMPSEY
BEFORE THE

HOUSE COMMITTEE ON ENERGY AND COMMERCE
SUBCOMMITTEE ON COMMERCE, MANUFACTURING, AND TRADE

Hearing on:
"A Tangle of Trade Barriers: How India's Industrial Policy is Hurting U.S. Companies"

JUNE 27, 2013

Good morning, Chairman Terry, Ranking Member Schakowsky and members of the Subcommittee on Commerce, Manufacturing and Trade.

I am Linda Menghetti Dempsey, vice president of international economic affairs at the National Association of Manufacturers (NAM), and I am pleased to provide testimony today on India's industrial policy and its impact on manufacturing and jobs in the United States. We believe "A Tangle of Trade Barriers" is an appropriate description of the significant challenges manufacturers are facing in the Indian market. We look forward to seeing those challenges addressed and resolved promptly.

The NAM is the nation's largest industrial trade association, representing 12,000 manufacturers in every sector and in all 50 states. Our membership includes both large multinational businesses with operations in many countries around the world and small and medium-sized manufacturers that engage in international trade. Manufacturing employs nearly 12 million Americans and is the engine that drives the U.S. economy by creating jobs, opportunity and prosperity.

Manufacturers in the United States have long been partners in India's growth and development. As India pursued economic reforms launched in the 1990s and opened important sectors to new investment, manufacturers expanded bilateral commercial ties. But over the last year and a half, we have seen a damaging pattern of actions in India that are discriminating against a wide array of products and putting at risk a bilateral trading relationship worth more than $60 billion in 2012.

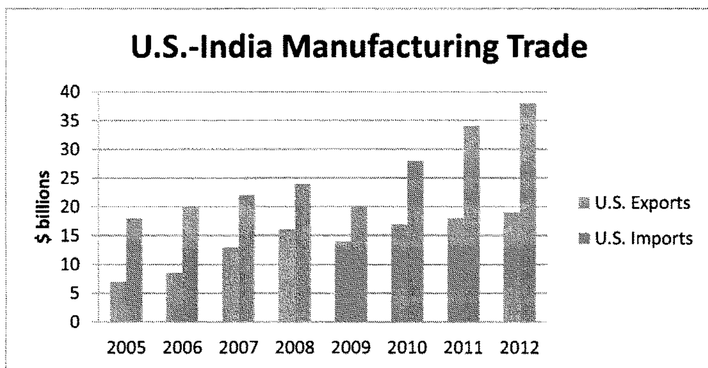
The U.S. government and manufacturers in the United States have expressed serious concerns about India's industrial policy repeatedly and without success. To demonstrate our resolve and to press for real results, the NAM and 16 other trade associations last week formed the Alliance for Fair Trade with India (AFTI). Together, we are asking the Obama Administration to address this issue at the highest levels of the Indian government and to end discrimination against American exports.

U.S.-India Trade and Investment

In 1948, India and the United States were two of the 23 original contracting parties to the General Agreement on Tariffs and Trade (GATT), the predecessor to the World Trade Organization (WTO). India played a significant role in the development of the GATT and then the WTO. The WTO represents the primary set of rules that govern U.S.-India trade and commercial relations.

Based on mutual respect for global trade rules, manufacturers in the United States have long sought closer economic ties with India. When India

began opening its economy in the 1990s, the U.S. and India commercial relationship took off. India benefitted from greater openness and closer commercial ties with the United States. Over the last decade, India's manufactured goods exports to the United States grew tenfold to $38 billion. The United States is now India's second largest export market. U.S. foreign direct investment in India totaled nearly $25 billion in 2011, of which $3.5 billion was in manufacturing.



The United States and India launched formal Bilateral Investment Treaty (BIT) negotiations in September 2008, although those negotiations slowed down due to the Obama Administration's review of the BIT template (the so-called Model BIT review), which was completed in April 2012. While the United States has been ready for more than a year to restart negotiations, no formal negotiating timetable has been established as India has embarked on actions contrary to such treaty obligations.

Manufacturers in the United States have faced challenges in the Indian market – from very high tariffs and weak intellectual property protection and enforcement to complex and expensive regulatory processes. U.S. exports to India face an average applied tariff more than six times higher than Indian goods face in the United States. India ranks 132 out of 185 countries on the World Bank's *Doing Business* report – below Papua New Guinea, Swaziland and Yemen. India also dropped to 100 out of 132 countries in terms of its global trade-enabling environment, according to the World Economic Forum's *Global Enabling Trade Report 2012* – behind China, Indonesia and Argentina.

Despite these challenges, manufacturers in the United States have viewed India as a promising market with great potential. However slowly, the Indian government was making progress toward reform and greater openness. India is the world's largest democracy and second-largest market by population. It has a young, dynamic and innovative workforce with a well-deserved reputation for quality production, particularly in key sectors. Today, India boasts a $1.8 trillion GDP – larger than Australia, Canada or Mexico. It is a rising middle income country, a G20 member and an important voice on the global stage.

India's Industrial Policy Actions

However, India's industrial policy is putting this growing trade and investment partnership at risk. Over the past year and a half, we have seen a damaging pattern of actions in India that are discriminating against U.S. exports of a wide array of goods. These actions have no other purpose but to favor

India's domestic corporations in strategic state-favored and state-advantaged sectors at the expense of manufacturing and jobs in the United States.

Consistent with a National Manufacturing Policy issued in late 2011, the Indian government is imposing local content requirements, denying or revoking patents and taking other steps to "induce the building of more manufacturing capabilities and technologies within the country" by forcing the local production of electronic, telecommunications, solar energy equipment, medicines and other "industries with strategic significance" and "industries where India enjoys a competitive advantage."

For example, India's Preferential Market Access rules would impose local content requirements on procurement of information and communications technology (ICT) products by government and private sector entities. Those rules require that as much as 100 percent of each covered product's market must be filled by manufacturers based in India, with the local content share for each product rising over time. The policy's coverage is so broad it could easily capture half of India's ICT market.

In the clean energy sector, India is requiring developers of solar photovoltaic projects employing crystalline silicon solar technology to use solar modules and cells manufactured in India. We understand India is considering whether to expand the scope of domestic content requirements in the solar sector to include solar thin film technologies. If this happens, it will make a bad situation far worse. Solar thin film technologies comprise the majority of U.S.

solar exports to India. The United States challenged several of these policies in February 2013 in the WTO.

India bans imports of remanufactured medical imaging devices and other equipment, while allowing sales of such equipment remanufactured in India. India recently denied or revoked patents for nearly a dozen innovative medicines. This includes medicines that were either distributed in India free of charge or sold at a small fraction of their cost in the United States. India imposes price caps on hundreds of medications. However, those caps do not apply to drugs Indian researchers develop.

On intellectual property more generally, India is a top country of concern for manufacturers in the United States. India continues to be a major channel for the export of counterfeits to consumers worldwide, with ineffective remedies due to major judicial delays and, in criminal cases, extremely low conviction rates. Furthermore, manufacturers are disturbed that India consistently promotes the view that trade secrets and patents impede innovation and the free exchange of technology. For all of these reasons, India remained on the United States Trade Representative's *Special 301* "Priority Watch List" in 2013.

Indian tax authorities increasingly are imposing discriminatory taxes on U.S. businesses, making them less competitive and triggering expensive litigation to resolve tax controversies. The uncertainty in India regarding tax administration has increased the cost and difficulty for foreign investors to do business in the country. Other critical concerns include barriers to foreign direct investment, particularly in the telecommunications sector, as well as

requirements to use local information infrastructure that inhibit cross-border data flows and India's anti-competitive export taxes on iron ore and its derivatives, which are designed to improve the cost competitiveness of its domestic steel industry – already the fifth largest in the world.

These actions are no way for a responsible stakeholder and rising global power to treat its second-largest trading partner. They are counterproductive to India's stated goals to attract capital and to develop its own innovative economy. Forcing local production and seeking to provide and create jobs through the rejection of basic property rights undermines India's ability to achieve the kind of long-term foreign investment that is vital for sustainable economic growth and job creation.

These actions are also inconsistent with international norms. Several appear to violate India's WTO obligations, including certain provisions of the GATT and the Uruguay Round agreements that prohibit local content requirements and require equal treatment for imported and domestic products. As a founding member of the GATT, India helped establish these fundamental "national treatment" rules some 65 years ago.

Without an immediate and purposeful response, India's industrial policy could spread and be applied to other products and sectors. It sets an unfortunate example that other countries are sure to follow. India's National Manufacturing Policy refers to other "industries with strategic significance" that, as far as we are aware, do not yet face new discriminatory treatment. It speaks of compulsory

licensing as a way to promote "technology acquisition and development" in the clean energy sector.

The Indian government is well aware of all these concerns, which have been raised repeatedly in Washington and Delhi by the U.S. government and businesses. They have been outlined in the annual *National Trade Estimate* and *Special 301* reports prepared by the United States Trade Representative and in the NAM's written statement to the House Ways and Means Trade Subcommittee in March 2013. Some are the subject of ongoing WTO dispute settlement proceedings.

Seeking Action and Results

The NAM is committed to resolving these concerns. To that end, we joined 16 other trade associations to form AFTI. This coalition unites a wide manufacturing and business community behind concrete solutions. Together, we are calling on the Obama Administration to raise concerns immediately at the highest levels of the Indian government. We understand Secretary of State John Kerry raised these issues during this week's U.S.-India Strategic Dialogue.

AFTI members want a level playing field and a fair shake in India. We want India to end its discriminatory industrial policy and unfair trade practices and ensure those practices are not repeated or extended to other products or sectors in the future. We look forward to the results of Secretary Kerry's visit to India. We hope and expect the Indian government will respond positively and work constructively with the manufacturing community to address and resolve concerns.

Until we see positive action, it will be difficult to convince manufacturers and others that India is ready to undertake the obligations of a BIT. While achieving a BIT based on the U.S. template with India would help address a significant number of concerns manufacturers are facing with the Indian government's actions, it is not clear that the Indian government has any intention of negotiating a strong, market-opening and enforceable treaty.

Given the complexity, time and resources that a BIT negotiation entails, it is critical for the U.S. government to determine if a strong BIT outcome is possible. If it is not, those resources might be best directed to negotiations with other countries. A BIT is not and should not be a political deal. It is a key part of the international rules-based system. Getting it right is vital to level the playing field and strengthen manufacturers' competitiveness in a challenging global economy.

A strong, bilateral trade and economic relationship is essential to achieving the strategic aims of India and the United States in South Asia and beyond. However, to have the kind of strategic partnership we all want, India must play by the rules.

Conclusion

The NAM looks forward to working with the subcommittee to identify solutions and improvements that can address these actions, increase opportunities for manufacturers and grow commercial activity between the United States and India.

Mr. TERRY. And now recognize Mr. Elliott, and you have 5 minutes.

STATEMENT OF MARK ELLIOT

Mr. ELLIOT. Thank you, Chairman Terry and distinguished members of the Subcommittee on Commerce, Manufacturing and Trade. The U.S. Chamber of Commerce appreciates your leadership and the opportunity to testify today on how India's industrial policies are hurting U.S. companies. Today I am going to focus my testimony on an array of IP concerns that the U.S. Business community has in India.

According to the U.S. Department of Commerce, U.S. IP industries account for $5 trillion of the Nation's GDP, 60 percent of exports and employ 40 million Americans. In short, intellectual property drives knowledge economies.

In 2010, the then President of India declared the next 10 years to be India's decade of innovation. Unfortunately, recent events in India suggest otherwise. Particular policy, regulatory and legal decisions have deteriorated IP rights in India, making India an outlier in the international community.

Last December, the Chamber released an International IP Index comparing intellectual property environments across 11 key markets. This was the first comprehensive national IP index and it ranked India consistently last behind Brazil, China and Russia in nearly every indicator. This trend is bad for India, it is bad for investment and it is bad for international trade.

I would like to provide the committee with a few specific examples of industries' concerns. With respect to the much needed copyright legislation that passed India's parliament last year, the end result failed to achieve the objective of the legislation, which was to implement the WIPO Copyright Treaty. The recording and music industry estimate lost revenue to piracy of $431 million in India. India's reported rate of PC software piracy in 2011 was 63 percent, an estimated commercial value of $2.9 billion.

India finds itself an outlier with respect to taxation when it comes to development centers within India. It currently assesses tax by allocating a share of the company's worldwide operating profits, despite the fact that the centers within India bear no financial risk and they don't own the resulting IP. This methodology is inconsistent with international practice and is not accepted by U.S. tax authorities, resulting in controversy and double taxation.

India has also shown disregard for intellectual property rights of the biopharmaceutical industry as stated. There have been at least five globally recognized patents that have been revoked, denied or compulsory licensed within the last 12 months.

While some may claim that these are unrelated policy, regulatory and legal decisions, the fact remains that these attacks on the pharmaceutical patents are only happening in India.

And this is not just about access to medicines, as some may have you believe. For example, in the case of Gleevec, Novartis provided the drug free of charge to 95 percent of the 16,000 patients suffering from leukemia. The remaining 5 percent were heavily subsidized. It is also worth noting that the Indian generic now charges

$2,100 annually for a generic version of the drug that Novartis was providing for free.

There are currently more than 5,000 innovative drugs in development around the world at the moment, and the industry has invested $5 billion in R&D since 2000. The medical innovation system is clearly working, and India's recent behavior undermines the global IP environment that protects and encourages this innovation.

For IP-intensive industries, the protection of IP rights is one of the most important factors companies consider when investing in a particular market. We have heard from a dozen industry and trade associations that the erosion of intellectual property rights in India will impact their members' decisions to invest there.

There are, however, leaders in India who recognize the importance of investment and innovation. On May 11, the current President of India noted that India's innovation bottom line is not very encouraging, as the number of patent applications filed annually in leading countries like the U.S. and China are roughly 12 times more than that of India. He called upon the private sector to increase their share of spending on research and development to the levels prevalent in other key markets such as the United States, Japan, and South Korea.

One very obvious way to increase this investment and innovation would be for the Indian Government to raise IP standards to the same levels that encourage business to invest in the United States, Japan, and South Korea.

We thank the subcommittee for holding this hearing, and we look forward to working with you to address business concerns in India.

Mr. TERRY. Thank you, Mr. Elliot.

[The prepared statement of Mr. Elliot follows:]

Statement of the U.S. Chamber's Global Intellectual Property Center

ON:	**"A Tangle of Trade Barriers: How India's Industrial Policy is Hurting U.S. Companies"**
TO:	**U.S. House Committee on Energy and Commerce Subcommittee on Commerce, Manufacturing, and Trade**
BY:	**Mr. Mark Elliot, Executive Vice President, Global Intellectual Property Center, U.S. Chamber of Commerce**
DATE:	**June 27, 2013**

The U.S. Chamber of Commerce is the world's largest business federation representing the interests of more than 3 million businesses of all sizes, sectors, and regions, as well as state and local chambers and industry associations. The Chamber is dedicated to promoting, protecting, and defending America's free enterprise system.

More than 96% of Chamber member companies have fewer than 100 employees, and many of the nation's largest companies are also active members. We are therefore cognizant not only of the challenges facing smaller businesses, but also those facing the business community at large.

Besides representing a cross-section of the American business community with respect to the number of employees, major classifications of American business—e.g., manufacturing, retailing, services, construction, wholesalers, and finance—are represented. The Chamber has membership in all 50 states.

The Chamber's international reach is substantial as well. We believe that global interdependence provides opportunities, not threats. In addition to the American Chambers of Commerce abroad, an increasing number of our members engage in the export and import of both goods and services and have ongoing investment activities. The Chamber favors strengthened international competitiveness and opposes artificial U.S. and foreign barriers to international business.

Positions on issues are developed by Chamber members serving on committees, subcommittees, councils, and task forces. Nearly 1,900 businesspeople participate in this process.

Summary

As the Chamber's intellectual property (IP) champions, the Global Intellectual Property Center (GIPC) strives to highlight IP as a critical driver of trade, jobs, competitiveness, investment, and overall economic growth.

In 2010, the then-President of India declared the next 10 years to be India's "Decade of Innovation." However, India's policies are inconsistent with their former President's statement. Over the last 18 months, particular policy, regulatory, and legal decisions have deteriorated their IP system, making India an outlier in the international community.

Last December, the Chamber released an International IP Index, *Measuring Momentum*, which compared IP environments across the globe. The study found that India consistently ranked last, behind Brazil, China, and Russia among nearly every indicator used in the study.

The GIPC has heard from over a dozen industry trade associations, representing tens of thousands of companies who have strong concerns about the deteriorating IP environment in India. These concerns include:

- The passage of copyright legislation, which failed to implement the World Intellectual Property Organization (WIPO) copyright treaty.
- The threat faced by film, music, and software piracy, which results in hundreds of millions of dollars in lost revenue.
- A national manufacturing policy, which allows Indian clean tech companies to call for compulsory licensing for patented technology of international companies.
- The recent policy, regulatory, and legal decisions, which undermined IP protections in the bio-pharmaceutical sector.

From the revocation of patents to the staggering rates of piracy, India stands alone as an international outlier in IP policies.

The GIPC urges the U. S. administration to defend global IP standards and utilize every diplomatic tool available to encourage the government of India to strengthen their IP protections and respect global IP standards. Further, we call on the Indian government to protect IP, encourage innovation, and return to the path of developing a knowledge-based economy.

Introduction:

Thank you Chairman Terry, Ranking Member Schakowsky, and distinguished members of the Subcommittee on Commerce, Manufacturing, and Trade.

The U.S. Chamber of Commerce appreciates your leadership and the opportunity to testify today on how India's industrial policies are hurting U.S. companies.

My name is Mark Elliot, and I am the Executive Vice President of the U.S. Chamber of Commerce's Global Intellectual Property Center (GIPC).

GIPC was established in 2007 as a division of the U.S. Chamber of Commerce, the world's largest business federation representing the interests of more than 3 million businesses of all sizes, sectors, and regions, as well as state and local chambers and industry associations.

Importance of IP:

As the Chamber's intellectual property champions, the GIPC strives to highlight the importance of intellectual property, or IP, in creating jobs, saving lives, advancing economic growth and development around the world, and generating breakthrough solutions to global challenges.

Particularly related to the jurisdiction of this committee, IP is a critical driver of trade, jobs, competitiveness, investment, and overall economic growth.

In fact, there are several studies that provide clear evidence and data to demonstrate the positive and cumulative economic impact of IP in the United States and abroad.

According to the U.S. Department of Commerce, U.S. intellectual property industries accounted for:

- $5 trillion or 34.8 percent of U.S. GDP;
- 60 percent of U.S. exports;
- 40 million American jobs; and
- These are good jobs, jobs that pay 42 percent higher wages than in other industries.

A study by the Organisation for Economic Co-operation and Development (OECD) concludes that a 1 percent change in the strength of a national IP environment, based on a statistical index, is associated with a 2.8 percent increase in foreign direct investment inflow.

In short, IP drives knowledge economies and creates jobs.

India's IP Environment:

In 2010, the then-President of India declared the next 10 years to be India's "Decade of Innovation."

The GIPC applauds the former President's recognition that innovation drives a knowledge-based economy. Notably, IP protections are critical to protecting innovation, encouraging investment, and spurring economic growth.

Unfortunately, India's policies are inconsistent with their former President's statement. Over the last 18 months, particular policy, regulatory, and legal decisions have deteriorated their IP system, making India an outlier in the international community.

Last December, the Chamber released an International IP Index, *Measuring Momentum*, which compared IP environments in 11 key markets.

This is the first comprehensive review of all policy sectors where IP is important. Our review covered all aspects of IP—patents, trademarks, copyright, and trade secrets. The study found that India consistently ranked last, behind Brazil, China, and Russia among nearly every indicator used in the study.

This trend is bad for India, bad for investment potential, and bad for international trade.

Multi-Industry Concerns:

I would like to provide a few specific examples of policies, across many industries, which are affecting the IP environment in India and causing concerns throughout the business community.

- With respect to the Copyright legislation that passed last year, though that was greatly needed, the end result failed to achieve the intent of the legislation, which was to implement the WIPO copyright treaty.

- The motion picture industry continues to face piracy on two significant fronts in India. First, India lacks appropriate legislation to deal with the sale of camcorder reproductions taken in movie theatres. In fact, India accounts for more than half of the forensic matches of illicit camcorder recordings in the Asia Pacific region. Secondly, India is among the top ten countries in the world for Internet piracy.

- The recording and music groups estimate a total of $431 million in lost revenue in 2011 to piracy.

- The reported rate of PC software piracy in 2011 was 63 percent in India, with a commercial value of unlicensed U.S. software in India estimated to be more than $2.9 billion.

- The green technology sector is also facing challenges. According to India's new National Manufacturing Policy, a domestic clean tech company has the option to ask the government to issue a compulsory license for a patented technology under one of the following two conditions: (1) if the patent holder is not providing the technology at a reasonable rate, or (2) if the technology is <u>not</u> being "worked on" in India.

- India's tax policies with respect to IP are part of this story and the GIPC urges the Committee's attention.

    - Specifically, I would call attention to India's tax policies related to compensation for captive development centers. U.S. multinationals generally assign routine development work to their India development centers. The development centers bear no financial risk for their development work and do not own any of the resulting IP rights. Accordingly, they are compensated on the internationally accepted cost-plus method. India's tax authorities are increasing their application of the profit-split method to determine development center compensation, effectively allocating a portion of the U.S. parent's IP profit to India. India's development centers operate similarly to other international development centers and should be similarly compensated on the internationally-

recognized cost-plus basis to reduce controversy and minimize double taxation.

- Within the bio-pharmaceutical industry, there have been many recent examples and a clear pattern of deterioration of IP rights:

    - In March 2012, the Indian Patent Board issued its first ever compulsory license on Nexavar, a Bayer drug used for cancer treatment. While the Patent Board claimed to be acting in accordance with the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, the fact that Nexavar is not manufactured locally is not a condition for issuing a compulsory license under TRIPS.

    - Pfizer has been fighting to keep its Sutent patent in force against revocation decisions of the Indian Patent Office in September 2012.

    - In November 2012, the Delhi High Court ruled against Roche in the patent infringement case for Tarceva, an innovative lung cancer drug. While the patent for the drug was valid, the Court ruled the generic did not infringe Roche's patent.

    - Most recently, in April 2013, the Indian Supreme Court denied a patent on a Novartis cancer drug, Glivec, even though the patent is recognized and valid in 40 other countries.

Not Access, But Exports:

Despite what some will have you believe, India's actions are not about access to medicines.

In many of these cases, the drug maker gave the drug to Indian consumers either free of charge or at a greatly reduced cost. In the case of Glivec, Novartis provided the leukemia drug to 95 percent of the 16,000 patient population for free, while the remaining 5 percent was heavily subsidized.

The annual cost for Glivec generic treatment is approximately $2,100 or three to four times the average annual income in India. Thus, it is actually more expensive for Indian patients to obtain access to these medicines after patent revocation than it was before.

Furthermore, while the Indian government claims their IP policies are about investment in innovation, India's expenditure on healthcare—6.8 percent of the total government expenditure (according to the World Health Organization)—is remarkably low and well below the expenditure of other developing countries.

For example, Brazil's government spends 10.7 percent and China spends 12.1 percent on healthcare. Thus, the Indian government's motivation may not be as altruistic as it seems.

In a report issued to their investors, a major pharmaceutical company called upon the Indian government to "announce a long term and unambiguous policy or guideline on compulsory license so that this important tool can be effectively used." This same company generates over 50 percent of its revenue from international markets. Clearly, some in India see compulsory licensing as a revenue generating opportunity.

India: The Outlier:

While some may claim that these are all unrelated policy, regulatory, and legal decisions, the fact remains that this is only happening in India.

From the revocation of patents to the staggering rates of piracy, India stands alone as an international outlier by global IP standards.

Investment:

For IP-intensive industries, the protection of IP rights is one of the most important factors to consider when investing in a particular market.

The GIPC has heard from over a dozen industry trade associations, representing tens of thousands of companies, across a variety of industries that the erosion of IP rights may impact their decision to invest in India.

There are leaders in India that recognize the importance of investment in innovation. On May 11, the current President of India noted that "India's innovation bottom line is not very encouraging as the number of patent applications filed annually in leading countries like U.S. and China is roughly 12 times more than that of India." He then called on the private sector to increase their share of spending on research and development to the levels prevalent in other economies such as the United States, Japan, and South Korea. The Chamber commends the President for his

vision and urges his government to implement IP policies to match the President's rhetoric.

To encourage private sector investment in India, the government must consider implementing IP protections at the same levels as enjoyed by the United States, Japan, and South Korea.

Conclusion:

India is a highly valued strategic partner for the United States and is an important market for U.S. companies.

International companies would like to continue to find ways to invest there. But, enough is enough.

The GIPC urges the Administration to defend global IP standards and utilize every diplomatic tool available to encourage the government of India to strengthen their IP protections and respect global IP standards.

Further, we call on the Indian government to protect IP, encourage innovation, and return to the path of developing a knowledge-based economy.

Thank you.

Mr. TERRY. Now Mr. Waldron, you are recognized for 5 minutes.

STATEMENT OF ROY WALDRON

Mr. WALDRON. Thank you, Chairman Terry and members of the subcommittee, for the opportunity to testify at today's hearing. My name is Ray Waldron. I am Pfizer's Chief Intellectual Property Counsel. In that capacity, I am responsible for overseeing and protecting Pfizer's IP portfolio worldwide.

Pfizer was founded in 1849 in New York and we are headquartered in New York today. Pfizer employs more than 90,000 individuals globally, including over 30,000 people in the United States.

I would first like to express Pfizer's appreciation for work by this committee to promote jobs, innovation and enhanced patient safety through the recent reauthorization of PDUFA. Through major research efforts, Pfizer is developing the medical solutions that will matter most to the people we serve. Specialized efforts in biosimilars as well as orphan and genetic diseases also illustrate our dedication to develop and deliver innovative medicines and vaccines that will benefit patients around the world.

Pfizer's R&D pipeline include several potential breakthrough medicines in Phase 3 clinical trials. These include treatments for breast cancer, cardiovascular disease, psoriasis and meningitis.

Unfortunately, recent events in India threaten our IP and undermine our ability to innovate, create jobs and provide faster access to lifesaving medicines. My testimony today will highlight Pfizer's serious concerns about these events, their impact on the U.S. and the industry and their potential spillover effect into other markets.

IP-intensive industries directly and indirectly support 40 million U.S. Jobs, drive over 60 percent of exports, and pay on average 40 percent higher than other industries that do not rely on IP.

PhRMA member companies invest over $54 billion annually in R&D. The path to a successful breakthrough cure is an arduous one. On average, it takes more than $1 billion and around 10 to 15 years of research to develop a new medicine. Our R&D ultimately becomes the IP that allows us to create new medicines. Effective IP laws and predictable transparent enforcement of these laws are essential.

For the biopharmaceutical industry, IP protection enables us to continue to invest in new research and development for medicines. Pfizer's future growth and the jobs that come with that growth will depend on our ability to engage on a level playing field in all global markets.

India is one such market. Pfizer has been operating in India for over 60 years. We have R&D and manufacturing facilities in Mumbai, Thane and Goa. We are a leading company in India in terms of innovation and employee satisfaction. Despite our commitment to India, over the past year we have seen a rapid deterioration of the innovative environment in the country. India has undermined patent rights for at least nine innovative medicines, including one of ours.

A recent history of compulsory licensing, discriminatory interpretation of the patent law, and refusal to enforce patents strongly indicate that India is an outlier in recognizing IP rights. These nine

innovative medicines have received patent protection in countries throughout the world. This recent history not only recreates significant uncertainty in the market but also undermines our ability to invest and compete fairly in India.

Pfizer's recent experience in India demonstrates a flagrant disregard of patent rights. In the last year, Pfizer has struggled to defend its patent for the compound sunitinib, the active ingredient in Sutent against efforts to revoke it. The patent has now been revoked twice under questionable legal theories and is currently back in force pending new proceedings before the Indian Patent Office, which is an administrative body under the Ministry of Commerce and Trade.

Each of the earlier revocations was reversed when Pfizer showed that its rights to a fair hearing and due process had been denied. During the back and forth of the revocation proceedings, one generic manufacturer launched its product in the Indian market, and as a result, the market is now flooded with 2 years' worth of supply from this manufacturer.

In order for there to be effective patent protection, the system of IP enforcement ought to include mechanisms to recall infringing goods from that market. I would also like to note that to ensure Sutent is available to patients who need it, Pfizer developed a patient access program in India which provides 80 percent of the patients taking Sutent with a complete or partial subsidy.

Pfizer exists to invent and manufacture high quality medicines to improve the health and well-being of patients around the world. To achieve this goal, effective, predictable and enforceable IP protections are essential. India's actions to undermine the incentives needed to make investment to develop new medicines and a hostile environment to IP will have a devastating impact on R&D investment in both the U.S. and India and cause significant harm to U.S. jobs and economic growth.

India's protectionist and discriminatory policies, which exploit U.S. IP to benefit their own industry requires an equally bold response. It is important that we view these actions for what they are, industrialist policies to benefit the competitiveness of India's own domestic industry.

We appreciate the focus you have provided on this issue today and look forward to working with members of this committee and other stakeholders to identify and implement solutions that will benefit innovators and patients in the U.S., India and worldwide. Thank you very much.

Mr. TERRY. Thank you, Mr. Waldron.

[The prepared statement of Mr. Waldron follows:]

Written Testimony of

Roy F. Waldron
Chief Intellectual Property Counsel
Pfizer, Inc.

Before the
United States House of Representatives Energy & Commerce Committee
Subcommittee on Commerce, Manufacturing and Trade

June 27, 2013

Thank you Chairman Terry, Ranking Member Schakowsky, and distinguished members of the subcommittee for the opportunity to testify at today's hearing on India.

My name is Roy Waldron, and I am Pfizer's Chief Intellectual Property (IP) Counsel. In that capacity, I am responsible for overseeing and protecting Pfizer's IP portfolio worldwide.

I would first like to express Pfizer's appreciation for the consistent efforts by the Energy and Commerce Committee to promote jobs, innovation and patient safety, including through the recent reauthorization of the Prescription Drug User Fee Act (PDUFA). PDUFA not only enhances our ability to provide faster access to new medicines to patients worldwide but it also enables the U.S. pharmaceutical industry to remain competitive in creating and delivering new cures to patients around the globe.

Recent decisions in India threaten to undermine our ability to innovate, create jobs and provide faster access to life-saving medicines. I testify today to highlight Pfizer's serious concerns about these decisions and urge the U.S. Congress and Administration to do all they can to make this issue a top priority in our bilateral relationship with India.

About Pfizer

Pfizer is a U.S.-based public company founded by two cousins in 1849 in New York and we are still headquartered there today. Pfizer's mission is to apply science and our global resources to improve the health and well-being of people's lives. We strive to set the standard for quality, safety and value in the discovery, development, and manufacture of medicines. We also collaborate with a wide variety of other stakeholders to support and expand access to reliable, high-quality healthcare around the world.

Pfizer employs more than 90,000 individuals worldwide, including over 30,000 people in the United States. We have a presence in most countries around the world and in all 50 States. Pfizer has 17 manufacturing sites across 11 states, including California, Michigan, North Carolina, and Tennessee.

Pfizer also has 34 R&D sites worldwide, 21 of which are in the United States, and R&D partnerships with 250 institutions. Last year alone, Pfizer spent nearly $8 billion on R&D, representing 14 percent of our revenues.

The Importance of Intellectual Property

Intellectual property is the engine that fuels the U.S. economy. According to a 2012 study by the U.S. Department of Commerce, IP-intensive industries directly and indirectly support 40 million U.S. jobs, drive over 60 percent of exports and pay on average 40 percent higher than other industries that do not rely on IP.[1]

The Pharmaceutical Research and Manufacturers of America member companies support more than four million jobs in the United States and invest over $35 billion annually in U.S. R&D, which represents 75 percent of worldwide R&D investments.[2] They also account for the single largest share of U.S. business R&D, representing nearly 20 percent of domestic R&D funded by U.S. business.[3] The path to a successful breakthrough cure is an arduous one. On average, it takes more than $1 billion and 10-15 years of research to develop a new medicine.[4] Only about one in 10,000 compounds that enter the drug discovery phase is ever approved by the U.S. Food and Drug Administration (FDA) and made available to patients.[5] And only two out of every 10 medicines will see a return on the investment spent on development. This lengthy research process is what leads to the development of life-saving and life-changing medicines.

Our R&D is ultimately protected by patents and other intellectual property, which provide the incentives necessary for further investments in the creation of new medicines. Effective IP laws and predictable and transparent enforcement of these laws are therefore essential to ensuring we have the resources to invest in researching and developing new treatments and cures for today's and tomorrow's diseases.

To put this into perspective, we file our patents in the very early stages of R&D, often a decade or more before the FDA review process begins. Thus, by the time we have submitted an application to the FDA, the patent life has already eroded by a meaningful extent. This significantly reduces the timeframe during which companies like Pfizer typically have to recoup our R&D investment of $1 billion before we lose the benefit of that investment. For the biopharmaceutical industry, IP protection enables our industry to continue to finance the research that advances the medicines available to patients around the world.

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[1] *See* Intellectual Property and the U.S. Economy: Industries in Focus (*available at* http://www.esa.doc.gov/Reports/intellectual-property-and-us-economy-industries-focus).

[2] Batelle Technology Partnership Practice, The U.S. Biopharmaceuticals Sector: Economic Contribution of the Nation (Columbus, OH: Batelle Memorial Institute, July 2011).

[3] National Science Board, 2012, "Science and Engineering Indicators 2012," Arlington VA: National Science Foundation (NSB 12-01).

[4] JA DiMasi, and HG Grabowski, "The Cost of Biopharmaceutical R&D: Is Biotech Different?" Managerial and Decision Economics no. 28 (2007): 469-79; PhRMA, "Drug Discovery and Development: Understanding the R&D Process" (Washington, DC 2007).

[5] Klees JE, Joines R., Occupational health issues in the pharmaceutical research and development process: Occup Med 1997; 12:5-27.

Opportunities for International Growth and India

With 95 percent of consumers living outside the United States, expansion to new markets is key to our ability to continue to grow, create jobs and identify new and innovative medicines. Pfizer's future growth and the jobs that come with that growth will depend on a level playing field in foreign markets.

India is a critical growth market for Pfizer. Pfizer has been operating in India for over 60 years. Our headquarters in India is in Mumbai; we have an R&D facility in Thane and a manufacturing facility in Goa.

Pfizer employs about 5,000 individuals in India, and these jobs are estimated to support another 15,500 jobs in the Indian economy. Over the last two decades, Pfizer has conducted more than 250 clinical trials in India involving almost 12,000 patients. Pfizer currently has almost 70 clinical trials in various stages ongoing in India with more than 1,200 participants.

Pfizer is a leading company in India in terms of innovation and employee satisfaction and has received awards and recognition throughout the years. For example, we recently received an award as best U.S. company operating in India under the manufacturing category. We have also been recognized as one of the best companies to work for by Business Today, a leading Indian magazine.

Pfizer strives to positively impact the health of people around the world. Our work in India is a prime example of how we seek to meet this goal. In 2012, for example, Pfizer promoted health literacy and disease awareness across 65 villages. We also partnered with the Spina Bifida Foundation to provide education grants and raise disease awareness among women in India.

Pfizer also offers patient access programs in India, which provide medically-eligible patients with treatment options based on socio-economic criteria. For example, 62% of patients with a particular cancer are treated with our drug Sutent and of those, 80% receive a complete or partial subsidy. Pfizer also offers education on managing the disease and medicine, counseling for patients and their families, and in some cases, patients receive nutritional support as well.

The Problem: India's Hostile Innovation and Investment Environment

Over the past year, the pharmaceutical industry has seen a rapid deterioration of the business environment in India. Since early 2012, India's policies and actions have undermined patent rights for at least 9 innovative medicines. Many of these medicines have received patent protection in most countries across the world, suggesting that India is an outlier in recognizing and enforcing patent rights. This is not only creating significant uncertainty in the market but it also undermines our ability to compete fairly in India, and our willingness to invest there.

Pfizer's story: Sutent

Sutent was first developed in the United States. The approval of Sutent in the U.S. in 2006 marked the first time that the FDA approved a new oncology product for two indications

simultaneously, gastrointestinal stromal tumors and advanced kidney cancer. The treatment has helped extend survival for this terminal illness beyond any previous treatment tested to date.

Pfizer's recent experience in India demonstrates a flagrant disregard of patent rights. In the last year, Pfizer has struggled to defend its patent for the compound sunitinib, the active ingredient in Sutent, against efforts to revoke it. The patent has now been revoked twice under questionable legal theories and is currently back in force pending new proceedings before the Indian Patent Office, an administrative body of the Ministry of Commerce and Trade. Each of the earlier revocations was reversed when Pfizer showed that its rights to a fair hearing and due process had been denied.

During the back and forth of the revocation proceedings, one generic manufacturer (NATCO) launched its product in the Indian market. As a result, the market is now flooded with about two years' worth of supply from this manufacturer. In order for there to be effective patent protection, the system of IP enforcement ought to include mechanisms to recall infringing goods from the market.

Other examples

I would also like to highlight a few additional examples to illustrate the significant challenges our industry is facing in India.

In another recent erosion of IP rights, India denied a patent under Section 3(d) of its Patents Act for Gleevec, Novartis' anticancer therapy that has been patented in 40 other countries around the world. In that case, the Indian Supreme Court interpreted an "enhanced efficacy" requirement for patentability in a way that led to denial of the patent. This decision is inconsistent with India's obligations under the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

Also, in 2012, India granted its first compulsory license for Bayer's kidney cancer medicine, Nexavar, allowing for the generic manufacture of this medicine. Often, compulsory licenses may be used by competitors as a means to obtain authorization to use or transfer technology developed by others without having to pay the substantial costs associated with developing and testing the product. These copiers are generally seeking to use the technology at a much-reduced cost. In some cases, compulsory licenses are inappropriately viewed by some governments as part of their industrial policy to establish domestic production or to reduce government expenditures for medicines.

India sought to justify its 2012 compulsory license, in part, on the basis of "failure to work the patent" because the product was being imported rather than manufactured locally. While compulsory licensing should only be used in certain extraordinary circumstances, the local manufacturing requirement initially used to justify the compulsory license was clearly inconsistent with India's international obligations. The standard for "working the patent" remains unclear.

Moreover, media reports have indicated that the Government of India is exploring its ability to issue additional compulsory licenses for the manufacture of other patented medicines, particularly three additional cancer drugs. This establishes a dangerous precedent not only in India but also to others who look to India as an economic leader.

One of the challenges with India's patent law is that it is riddled with pitfalls for the pharmaceutical patent owner —and some provisions have to date been interpreted to the detriment of innovators. For example, Section 8 of the Indian Patents Act, a provision with vaguely-worded requirements on reporting of activity in other patent offices around the world, could be used to render patents invalid if applied in an expansive and exacting manner as has been threatened. This is of growing concern and ought to be carefully watched.

The above decisions and actions illustrate the erosion of the patent system in India and create disincentives to conduct further research to identify new life-prolonging and life-saving therapies in the future. A patent is only meaningful, if the rights holder can count on the right being enforced in a predictable and transparent manner. The current protectionist industrial policies are inconsistent with India's commitment to the global trading system and the laws that govern it.

The Economic and Public Health Impact of India's Decisions

The impacts of India's decisions are significant.

First, they are a significant blow to the IP system that drives U.S. growth and innovation worldwide. In the case of our sector, India's actions undermine the incentives needed for pharmaceutical companies to make investments required in developing new medicines. The chilling effect in global R&D investment as a result of India's intellectual property policies could have a direct impact on jobs and investment in the U.S., given that the U.S. is the largest recipient of spending on global R&D. Moreover, it could mean less investment in new treatments for diseases that plague our population.

India's recent decisions regarding the pharmaceutical industry also represent a further erosion of the overall IP environment in India, which should be of concern to other IP-reliant industries. India's disregard for intellectual property protection and enforcement is not limited to the pharmaceutical industry. In fact, a cross-sectoral IP Index published by the U.S. Chamber of Commerce's Global IP Center last year ranked India last of 11 countries in IP protection and enforcement across a variety of sectors.[6]

Second, India's recent IP decisions discriminate against U.S. companies and hinder our ability to compete on a level playing field in India. At the same time as India is rolling back protections for U.S. innovators, Indian pharmaceutical companies enjoy unfettered access to the U.S. market and have grown their U.S. sales dramatically. For example, three of India's major pharmaceutical companies generated approximately 50 percent of their revenue from sales in the

[6] *See* Measuring Momentum, the GIPC International IP Index (*available at* http://www.theglobalipcenter.com/measuring-momentum-the-gipc-international-ip-index/).

United States.[7] American companies should be afforded no less protections than their Indian competitors.

Third, India's short-sighted approach will do more harm than good for its own patients, innovators, and economic development. If India continues to erode IP rights and enact protectionist policies, the result could be significantly reduced foreign investment in India as well as delays in getting Indian patients access to the newest medicines. Moreover, such policies also promote an environment for India's own pharmaceutical companies, that is hostile to the development of innovative medicines, including for diseases that are especially prevalent in India and its region, such as tuberculosis, diarrheal disease and water-borne illnesses.

And fourth, these decisions threaten to establish a dangerous precedent for other countries seeking to promote their own protectionist industrial policies. India is often seen as a leader amongst emerging economies and its governments to set the right tone to promote innovation—including indigenous innovation in India If we are to avoid permanent harm to our ability to innovate new life saving and enhancing inventions, it is essential that we take all necessary measures to avoid a contagion effect.

A Call to Action

The international IP system is being challenged on a number of fronts. Recently, a high level Commission, co-chaired by Dennis C. Blair and Jon M. Huntsman, Jr., released a report on the theft of U.S. Intellectual Property. In that report, the Commission predicts that as companies mature in emerging markets over the long term, these markets "will develop adequate legal regimes to protect the intellectual property of international companies as well as domestic companies." At the same time, the Commission wisely cautions that "[t]he United States cannot afford to wait for that process... and needs to take action in the near term to protect its own interests."[8]

India's protectionist and discriminatory policies, which exploit U.S. IP to benefit its own industry, require an equally bold response. This is vital to not only promote the incentives to deliver new cures and medicines around the globe but also to protect our overall IP-based system and the job creation that this system supports.

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[7] *See, e.g.*, Press Release, "Dr. Reddy's Q1 FY13 Financial Results," July 19, 2012 (*available at* http://www.drreddys.com/media/popups/q1fy13_results_19jul2012.html); Press Release, "Sun Pharma reports a strong quarter," August 10, 2012 (*available at* http://www.sunpharma.com/images/finance/FY13%20Q1%20Press%20Release%20Financials.pdf); Press Release, "Q1 FY13," August 10, 2012 (*available at* http://www.wockhardt.com/pdf/QUARTERLY-REPORT-(Q1)-fl2ee.pdf).

[8] *See* The IP Commission Report (*available at* http://www.ipcommission.org/).

We recommend that the following steps be taken:

1) The U.S. Congress and Administration should work to elevate India IP issues to the highest levels of all U.S.-India bilateral dialogues to seek resolution to these concerns.

2) The U.S. government should raise concerns in every available bilateral and multilateral forum to send a strong signal to the Indian Government and to other governments that such actions will not be taken lightly.

3) We urge the U.S. government to explore all available diplomatic, trade, policy and legal tools and seek to engage like-minded partners such as the European Union, to address India's protectionist policies and ensure equal treatment for U.S. and Indian companies.

4) The U.S. must continue to demonstrate strong leadership in promoting effective and enforceable IP rules of the highest standard around the world, including in the Trans-Pacific Partnership (TPP) and the Trans-Atlantic Trade and Investment Partnership (TTIP).

Conclusion

Pfizer is in the business of creating high quality medicines and making these medicines available to patients as quickly as possible. To achieve this goal, effective, predictable and enforceable intellectual property protections are essential. India's recent actions threaten to undermine our ability to innovate and save and improve lives. It is important that we view these actions for what they are: protectionist policies to benefit India's own domestic industry. We appreciate the focus you have provided on this issue today and look forward to working with Members of this Committee and other stakeholders to identify and implement solutions that will benefit innovators and patients in the U.S., India and worldwide.

Mr. TERRY. And now Mr. Hoffman, you are recognized for 5 minutes.

STATEMENT OF ROBERT HOFFMAN

Mr. HOFFMAN. Thank you, Mr. Chairman, and thank you to the members of this subcommittee, Vice Chairman Lance. We appreciate the opportunity to appear today. I am Robert Hoffman, Senior Vice President for the Information Technology Industry Council, ITI. ITI represents 52 of the most dynamic innovative companies in hardware, software, and services. We obviously, given the strong presence of IT in India, consider the bilateral relationship between U.S. and India to be an extremely important one for our industry.

For the overall economy in the United States, there is no question that the bilateral economic ties have been relatively recent in development. It certainly can be said that the big reason why that is the case is because for at least the first 44 years of Republic of India's existence, Cold War politics and a socialist largely closed economy really made the development of commercial ties very difficult. All of that changed in the 1990s, when in response to economic and monetary crisis, the government of India took steps to gradually open its economy. It also coincided, by coincidence, with the information technology boom of the 1990s and the development of the information and communications technology industry in India.

There is no question that the combination of market opening reforms and letting the IT industry in India operate in an open fashion, utilizing market incentives and taking advantage of investments in education and an entrepreneurial and innovative team of people in the IT industry, it has had some extraordinary significant effects in India. It has literally helped move hundreds of millions of people off of extreme poverty. It has also helped it triple the annual GDP growth rate in India all within two decades.

If liberalization is allowed to continue and market-based incentives are allowed to move forward and innovators and entrepreneurs in India are allowed to flourish, some have estimated that India's middle class can number well over 500 million people. Put that in prospective, when the U.S. population is 300 million people.

This is all very exciting, and from our perspective, as India considers options to develop a manufacturing base, our recommendations are pretty simple. You have seen market-based innovation work in the IT sector. You have seen what your innovators and entrepreneurs can do in India. Turn them loose. We are Exhibit A that it can work.

Unfortunately, and this leads to my second point, and as many of my colleagues here on the panel have already demonstrated, India appears to be moving in the opposite direction and is preparing to throw its economy in reverse and undermine the gains that we have seen in the last two decades. Let me provide a couple of examples.

Frankly, I have been to India several times and I have to tell you that one of the frustrating aspects of visiting with government officials is that the economic success stories of the last two decades haven't been fully grasped within the bureaucracy in India. We see it in the random and oftentimes troubling enforcement measures

taken by tax and customs officials. Another example is the fact that India is sitting right now on the sidelines while we are negotiating expansion of the Information Technology Agreement.

The ITA, which was agreed to in the mid-1990s, was extremely helpful to India as it pursued its objectives in IT. An expanded ITA would actually help their efforts to advance their manufacturing initiatives. So we are very surprised to see them on the sidelines.

Last but not least, we are very troubled by their recent efforts to impose what amounts to a forced manufacturing policy on electronics products in India. The fact of the matter is, right now, if you want to sell to the government of India, you have got to manufacture electronics products within the Republic of India, and there are some serious concerns that is this policy is going to be expanded to the private sector and all you have to do is look at the Economic Times of India's front page story today that talks about how it plans to expand this policy with telecom operators, and if it is allowed to continue, they will expand this forced manufacturing requirement, you know, all the way into other sectors, including financial services and energy.

So, we are obviously very concerned. We are trying to encourage the government of India, working with people like the—organizations like the U.S. Chamber of Commerce and NAM and other institutions worldwide, to get India on the right track, toward more economic liberalization utilizing market-based incentives. We have to be very careful that if they go down the road of forced manufacturing, it could have a contagion effect and encourage other countries to do the same thing.

The fact is, if you look at countries like China and Brazil, forced localization is a pretty addictive drug, and frankly, what we really need here is a little policy intervention. We consider India a valued friend, collaborator, and competitor, but the fact of the matter is friends don't let friends get addicted to forced localization.

So, thank you, Mr. Chairman, and we appreciate again the opportunity to appear here today.

Mr. TERRY. Doesn't necessarily fit on a bumper sticker, but——

Mr. HOFFMAN. No. Give me a couple of days, though.

Mr. TERRY. All right. Thank you, Mr. Hoffman.

[The prepared statement of Mr. Hoffman follows:]

Information Technology
Industry Council

Testimony of Robert Hoffman
Senior Vice President for Government Affairs
Information Technology Industry Council (ITI)

Subcommittee on Commerce, Manufacturing, and Trade
Committee on Energy and Commerce
U.S. House of Representatives

June 27, 2013

Mr. Chairman, Ranking Member Schakowsky, and members of the Subcommittee, thank you for the opportunity to testify at today's hearing on market access challenges in India. I am Robert Hoffman, Senior Vice President of Government Affairs for the Information Technology Industry Council, known as ITI. ITI is a global trade association representing 52 of the world's most innovative, forward-thinking technology companies.

Today's topic -- our bilateral commercial relationship with India -- is certainly timely. Earlier this week, Secretary Kerry and India's Foreign Minister, Shri Salman Khurshid, met in Delhi for the fourth U.S.-India Strategic Dialogue. Their joint statement at the Dialogue's conclusion touched on a number of important issues central to today's hearing.

The Strategic Dialogue was preceded by a crescendo of letters and statements from policymakers and thought leaders, highlighting fundamental concerns with numerous existing or proposed economic policies coming from Delhi. The commercial challenges U.S. businesses face in India was even front-and-center at the Senate Finance Committee's confirmation hearing for Mike Froman as U.S. Trade Representative.

Frankly, all of this is no surprise. The U.S.-India economic relationship is strategically important and yet it's a relationship not well understood. That is certainly true for the information and communications technology, or ICT, industry. Many of the extraordinary innovative success stories in the global ICT industry during the past two decades have taken place in the United States and India. Thanks to the quality of skilled American and Indian talent, the United States and India are critical links in nearly every global ICT product development, supply, and support chain.

One could argue the ICT industry is a microcosm of what is both good and frustrating about the U.S.-India economic relationship. Much like the ICT industry, our two countries often compete against but collaborate with each other, and the opportunities generated as a result of competition and collaboration benefit the economies not only of both countries, but also the global marketplace. Strangely and unfortunately, despite this extraordinary progress -- progress rooted in India's gradual movement toward a more open economy -- the Government of India is pursuing and considering policies that are certain to reverse its past successes as an emerging economic power, reduce its future capacity to invest in other economies, including the U.S., and undermine the ability of U.S. and other foreign ICT companies to compete fairly in India.

Let me highlight several very troubling examples that underscore these points:

- Last year, India rolled out its Preferential Market Access initiative, or PMA. One key component of the initiative is to force the public and private sectors in India to procure domestically produced ICT products and services. While India has gone forward with implementing localization requirements on public sector procurements, it is poised to extend them into the private sector, starting with telecommunications operators.
- India continues to stand on the sidelines during the on-going negotiations to expand the Information Technology Agreement (ITA), a highly successful trade pact to which India, the United States, and 74 other World Trade Organization (WTO) members are party.
- Global technology companies face numerous regulatory challenges and persistent remnants of ambivalence toward business from Indian government officials. We experience it in a regulatory and enforcement context, including random and often disturbing enforcement actions by officials in tax and custom matters. The excessive number of large-dollar tax controversies in India demonstrates a clear need for improvements in the fairness, predictability, transparency, consistency, and efficiency of Indian tax law, collection, due process, and dispute resolution.
- A range of problematic testing and certification requirements on our products are unworkable and veer markedly from global norms. These new requirements were developed with limited industry consultations; deviate in significant and impactful ways from international norms; cannot be implemented as published due to the lack of testing capacity and infrastructure; and will make it nearly impossible for companies to import a wide range of ICT products. Fortunately, implementation of these new requirements has been delayed, and we have urged the Government of India as recently as a few weeks ago to extend this delay even further to consider approaches that are consistent with international standards and practices.

With respect to its policies regarding PMA and ITA expansion, India rationalizes these choices as central to the development of its own advanced ICT manufacturing capabilities, and the future growth of its middle class. We certainly do support India's objective to build a strong manufacturing base, but some of its policy choices to achieve this objective are needlessly putting India at odds with its global partners and also with its own larger economic initiatives that advanced its emergence on the global stage.

In fact, it's important to put India's PMA and ITA policies in the context of its recent economic history, including what has been until recently a positive and constructive evolution and advancement in our own commercial relationship with India. This helps to underscore the significance of these policies and the troubling risks they present to both countries.

While both India and the United States have a shared commitment to democratic principles that go back even before India's independence in 1947, the growth of the bilateral economic relationship has been relatively recent, and has been driven largely by India's turn toward market-based economic policies in 1991, and the emergence of its globally competitive software and services sector. The economic bonds between our two countries have taken root and become more dynamic as India's innovators and entrepreneurs started to take hold of that country's destiny.

When the ICT industry talks about public policies that matter most to advance innovation, the conversation usually begins with the need to preserve an entrepreneurial ecosystem. By and large, U.S. policymakers understand the importance of this ecosystem. It's been a part of our national DNA since Jamestown and Plymouth Rock. That said, we have to reinforce the importance of the ecosystem or we risk it being taken for granted. That's a big reason why ITI exists. We welcome the opportunity to work with policymakers to advance our innovative potential. At the same time, to effectively do our work, we also find ourselves opposing polices that risk hindering or even destroying that potential, most notably policies that restrict the flow of ideas, innovations, and commerce.

The reverse is certainly true as well. In a closed, stagnant, struggling economy, the best policies are those that unleash an open, entrepreneurial ecosystem and tear down barriers to the development and production of goods and services. During the last 25 years, India has been gradually making progress toward advancing such an ecosystem.

While innovators and entrepreneurs have been openly celebrated in the United States for centuries, that's only been recently the case in India. Throughout the last few centuries, India's innovative potential has been held back by a combination of colonial administration and, since its independence, economic dysfunction. Both factors also limited the development of a thriving trade relationship between the United States and India.

For its first 45 years of independence, India's economic governance adhered to a socialist, centralized framework. Government-imposed domestic production schedules and licenses, and restrictions on imports and foreign investment were key barriers to economic progress. For example, as recently as thirty years ago, an Indian computer services firm seeking to import a U.S.-made computer would have to wait as long as three years for an import license, and once granted, the firm faced a tariff of 101 percent.

But, in 1991, India was forced to reassess its closed economic model when it confronted an economic perfect storm: high oil prices, the collapse of its largest trading partner, the Soviet Union, and a foreign exchange crisis.

The government responded with a series of economic shocks of its own to put the economy on a more open, liberalized course, and helped to give rise to a global software and services sector, including:

- Severe reductions in tariffs and controls on imports. An Indian computer services firm that once had to wait years to import a computer could buy the electronics, hardware and software it needed at competitive prices;
- Devaluation of India's currency, the rupee. This made the prices of India's services exports competitive in global markets -- also good news to India's software and services industry;
- Increased access to international capital markets to fuel Indian-based startups and business expansion;
- Opening of India's equity markets to foreign institutional investors;
- Encouragement of foreign direct investment in joint ventures;

- Allowance of full 100% foreign equity in key economic sectors, one of them being information technology; and,
- Tax and incentives at the federal and state level targeted at foreign-owned ICT companies.

The overall effect of these reforms was extraordinary. Average GDP growth has more than tripled. Poverty has been reduced dramatically, as an estimated 431 million Indians moved out of extreme poverty from 1991 to 2009. Continued economic liberalization has the potential during the next two decades to triple Indian incomes and boost India's middle class to more than half a billion people.

Liberalization was one among a number of key factors that unleashed the Indian IT software and services industry, including tax and investment incentives, access to a deep pool of English-speaking engineering talent, and revolutions in global telecommunications. India's software and services sector has played an instrumental role in unleashing the productive potential of numerous sectors, such as financial services, health care, energy, transportation, retail, and entertainment. The ability of a financial institution to transfer billions in investment capital at the click of a mouse, or a consumer to buy an airline ticket at the touch of a smart phone screen, are due in large part to a global ICT chain that is dominated and operated 24/7/365 by research, development, and maintenance centers in the United States and India.

A key policy decision that helped India's software and services industry was India's decision to sign the ITA in 1997. That decision-making process is insightful given the policies India is pursuing today. India at first hesitated about joining the ITA, fearing that lower ICT tariffs could harm its fledgling manufacturing sector. But the computer software and services industries understood the critical importance of having unfettered access to innovative, affordable ICT technologies from around the world. Ultimately, India's leadership made the wise decision to join this ground-breaking agreement, and it has served to benefit India's businesses and consumers.

That same ITA debate is being repeated today on the topic of ITA expansion. And it's a reminder that, while economic liberalization has ushered in dramatic changes in India, it is far from being embedded in India's DNA. Foreign investment and market access barriers exist across a number of sectors, and the benefits of a market- and innovation-driven economy are not uniformly understood and appreciated throughout India's vast bureaucracy.

Strangely, critics of a more open economy have sought validation of their point of view from a recent slowdown in India's economy. Once nearing 10 percent annual GDP growth just a few years ago, India's economy grew just 5 percent at the end of its fiscal year in March -- after a 6.2 percent increase the previous year. Foreign Direct Investment also has fallen. The Press Trust of India recently reported that India received roughly $14 billion in the first nine months of its most recent fiscal year, compared to $23 billion in 2011-12.

While the software and services sector will continue to be a major driver of India's exports and growth, Delhi sees robust manufacturing as central to its future economic development. Given the extraordinary role liberalized, and incentive-based economic policies played in launching India's ICT sector, the logical policy choice would be for India's emerging manufacturing to follow the same playbook.

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That's not what we're seeing. India effectively threw its economic policies in reverse in February 2012, when it adopted a forced localization policy as part of its larger PMA initiative. This policy imposes local content requirements of up to 100 percent on procurements of "electronic products" by the government. While India has threatened to extend the PMA to private sector entities with "security implications for the country," as of yet it has not done so -- but it is poised to do so. Of course, India rationalizes its decision to pursue a mandated made-in-India policy in order to develop India's advanced manufacturing base to boost domestic employment. However, the policy is also defended as a means to achieve greater product security.

More than a half-dozen guidelines to implement the PMA localization mandate have been announced and most have focused on government procurement. Although India is a member of the World Trade Organization (WTO), it is not a signatory to the Government Procurement Agreement (GPA), and thus can apply forced localization requirements to government procurements.

Last October, however, this fundamentally bad policy became worse when India's Department of Electronics and Information Technology issued draft guidelines that would impose forced localization requirements on purchases of a defined list of telecom products by private-sector telecom operators/licensees.

While India has yet to implement a forced localization policy on the private sector, based on a recent visit to India, I can report the following:

- The Government of India appears poised to move forward on its proposed forced localization initiative on telecom operators.
- The Government of India is considering additional forced localization policies in other key sectors, including financial services, transportation, and energy. This would effectively cover more than half of all major electronics purchases in the Indian marketplace.
- Industry stakeholders have informed us that the Government of India is considering content requirements that extend beyond hardware and into software and intellectual property.

The PMA localization requirement raises significant questions regarding India's current and future commitment to further market liberalization reforms, as well as to the rules-based trading system established under the WTO, including the fundamental principle of "national treatment." India has suggested it intends to invoke national security as the grounds for imposing local content requirements on ICT purchases by the private sector. Doing so would set a dangerous precedent for other WTO signatories to mirror.

Of course, the United States is not the only country with concerns about India's forced localization policies. Governments in Tokyo, Brussels, Seoul, and other capitals have urged India to drop the WTO-inconsistent components of its PMA localization policy. ITI has assembled a business coalition from around the globe to elevate concerns with Delhi about its PMA policy. Many members of Congress, including Republican and Democratic members of the Energy and Commerce Committee, have urged India to avoid taking the forced localization road.

No one should fault India's desire to build robust ICT and ICT-enabled manufacturing sectors. In fact, India's commitment to advance its economy and grow its middle class will create numerous opportunities for increased trade for U.S.-based industries, including ICT.

However, given India's international influence, the broader ramifications of trade protectionism could induce other countries to take similar actions. And that leaves us with a race to the bottom.

What will all this mean for our industry? Just in India, if the government chooses to expand forced localization requirements into other key industries, it could easily capture $9.3 billion, or roughly half, of India's $20.5 billion ICT market. And that's just in India. This policy, if allowed to stand, would encourage other governments to adopt similar policies to close off their own markets to foreign competition. This would create what we call the "contagion effect," and it's real.

As I noted at the beginning of my testimony, one of the countries with the potential to be the most adversely affected by India's PMA policy is India herself. It will further discourage foreign ICT entities from investing in India, disrupt the global supply chain of ICT vendors that many Indian businesses helped to create and build, raise the price of ICT goods for Indian consumers, and restrict India's access to the best ICT technologies, including those that would improve cybersecurity.

Similarly, India's refusal to join the ITA expansion talks in Geneva also undermines India's economy. From 1996 to 2008, total global two-way ITA product trade increased more than 10 percent annually, from $1.2 trillion to $4.0 trillion. In the process, the ITA has helped to drive innovation, accelerate productivity, increase employment, lower consumer prices, and bridge communities across the globe in ways unimagined 16 years ago, when the agreement was forged. Yet, while the high-tech sector has exploded with new and improved products since the ITA came into force, the product scope of the agreement has never been expanded.

So it is puzzling to hear some in the Indian government express "buyer's remorse" for joining the initial agreement in 1997. The ITA has played a pivotal role in building India's IT-enabled services industry by providing access to myriad innovative and affordable ICT equipment through tariff elimination. In recent years, as India's ICT services industry has become more advanced, India's growth rates of ICT goods exports have far exceeded imports. According to the WTO, from 2005-2010, the annual rate of India's tech goods export growth was 35 percent versus only 10 percent for tech goods imports.

Just as India's software and services industry benefitted from competitive-priced products ranging from computers to routers to build its ICT industry infrastructure, its emerging manufacturing industry also would benefit from similar foundational economic building blocks, such as ICT goods. To impose tariffs on these goods would be counterproductive to promoting a strong, competitive, advanced manufacturing industry. Indeed, one study done by Indian economists found that for every $1 in tariffs India imposed on tech imports (in the years before joining the ITA), it incurred an economic loss of $1.30 due to decreased productivity.

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Other emerging economies are embracing ITA expansion, from Malaysia to Costa Rica to Croatia. One must ask, after more than two decades of building its global economic leadership, will India now stand by and let its competitors reap the investment and trade benefits of being more fully integrated into the global supply chains that will inevitably flow from an expanded ITA?

Bottom line, the policy choices being made in Delhi suggest a significant reversal in India's broader growth strategy, and potentially, a similar dimunition in our bilateral economic ties. Moreover, many of these policies appear specifically designed to disadvantage U.S. and foreign ICT companies seeking to compete fairly in India, while working to potentially disadvantage India's own economy. The enlightened, progressive economic policies of two decades ago that enabled India to become a global powerhouse in software and services now are at risk of being undermined, if not dismantled.

Yes, we could let all this play out and let the WTO diplomats resolve issues like the misguided PMA policy. This would be good for trade lawyers, but not for industry entrepreneurs. A WTO-imposed solution would take years to implement, and would undermine ICT product innovation and development for India and the U.S.

That's why this week's joint statement at the conclusion of the Strategic Dialogue -- and the upcoming trip to India by Vice President Biden -- offers the hope that we can resolve these issues through bilateral mechanisms and collaboration. Given the critical importance of the Indian and American markets to the entire tech sector, reaching agreements among stakeholders short of pursuing potentially disruptive unilateral policy options serves all our interests. So we deeply appreciate your decision to convene this timely hearing this morning. We are committed to continuing the dialog with India in an effort to find better solutions.

As I noted earlier, India is both competitor and collaborator with the United States and many other countries. Global competition is the rising tide that raises all boats. What's at stake is the shared commitment to the economic ideals that have unleashed innovators and entrepreneurs in India, and reinvigorated innovators and entrepreneurs here in the United States. That is why we urge the U.S. government, and like-minded governments around the world, to intensify their efforts to get India back on a track that once again embraces market-driven approaches. "Forced localization" policies, such as the PMA, taken to their logical conclusion mean the end of vibrant global supply chains. They cannot stand. They are a real threat to our economic model, to the American economy, and to American jobs.

We recognize that India faces many daunting economic challenges. We all do. Our great hope is that we can work together to meet those challenges in the spirit of collaboration that has made the last two decades so enriching and rewarding for both our countries. Our industry considers India a close friend and valued partner. But friends don't let friends drive forced localization policies. It's an addictive but damaging practice. Friends and partners owe it to each to have frank and honest discussions when differences arise. It is in that spirit that I appear before the Subcommittee today.

Thank you.

Mr. TERRY. Mr. Smirnow, you are now recognized for 5 minutes.

STATEMENT OF JOHN SMIRNOW

Mr. SMIRNOW. Mr. Chairman, and members of the committee, thank you for the opportunity to appear before you today. The Solar Energy Industry Association, or SEIA, represents over 1,000 solar businesses operating within the United States, including leading U.S. solar manufacturers and exporters. Today, solar employs over 120,000 Americans and more than 5,600 companies, most of which are small businesses. Solar is also one of the fastest growing industries in American.

My testimony today will focus on India's growing use of an industrial policy which discriminates against U.S. Solar exports, thereby providing an unfair competitive advantage to India's domestic solar manufacturers.

With some of the best solar resources in the world and the cost of solar continuing to decline, India's solar sector is poised for explosive growth, providing an important export opportunity for U.S. solar manufacturers. Indeed, over the past few years, as the chairman indicated in his opening statement, U.S. solar panel manufacturers have contracted to supply hundreds of millions of dollars of solar exports to India.

Importantly, most of these exports are comprised of U.S. solar panels based on thin film technology. A company called First Solar, headquartered in Arizona with manufacturing operations in Ohio is the leading global producer and innovator of this technology, and this is indeed a leading, cutting edge U.S. technology.

At the same time, however, India's solar policies have increasingly turned inward. In 2010, India adopted a local content requirement as part of the country's National Solar Mission. While we fully support India's desire to promote solar manufacturing both as an economic development tool and a solution to climate change, India's government support measures must be consistent with India's international trade obligations. India's solar local content requirement, however, is a direct violation of these obligations.

One of the arguments we hear in support of the local content measure is that it is necessary to nurture the growth of a young industry, particularly in an environment of intense global competition. But while local content requirements may provide some protection for domestic manufacturers, they also stifle innovation, limit a country's access to next-generation technologies and increased costs, not to mention the fact that local content requirements are explicitly prohibited by global trading rules.

Returning to the specifics of India's solar industrial policy. The national solar mission is divided into three phases. Under the first tranche of Phase I, India required that eligible products—projects based on crystalline silicon technology, that is the other half of the solar panel industry, versus thin film, and that is where the U.S. has a technological advantage, in this first phase, India required that one-half meet a local content requirement for cells, and solar cells are the heart of a solar panel for this technology.

So while U.S. companies could sell cells into India—or they could sell modules but they weren't able to sell cells, U.S. origin panels were thus barred from competing.

For the second tranche of Phase I, India broadened this local content requirement to mandate that National Solar Mission products use only crystalline silicon cells and panels manufactured in India, a significant lost opportunity for U.S. exports. Looking forward, we are concerned that India will expand its local content requirement yet again to cover thin film technology, effectively targeting hundreds of millions of dollars of U.S. exports. Our only hope is that the U.S. Government's recent decision to initiate a WTO case against India will eventually cause India to reverse course.

The U.S.-India dispute follows on the heels of a recent WTO finding that Ontario, Canada's local content requirement for solar goods, substantially similar to India's, violated Canada's WTO obligations. In response, Canada has indicated that the solar program will be brought into compliance with the WTO decision, which we presume means that Canada will remove the local content provision. India should follow Canada's lead today and remove the local content provision from its National Solar Mission.

As important context, the U.S. Government first tried to establish a collaborative dialogue with India regarding the local content requirement but was rebuffed. The U.S. case was therefore a last ditch effort to get India to the table.

I want to make clear that we support the overall objectives of India's National Solar Mission and its focus on growing a solar manufacturing base. We just don't support the discriminatory aspects of it.

That concludes my remarks. I will be happy to answer any questions. Thank you.

Mr. TERRY. Thank you very much.

[The prepared statement of Mr. Smirnow follows:]

TESTIMONY OF JOHN SMIRNOW
VICE PRESIDENT OF TRADE & COMPETITIVENESS
SOLAR ENERGY INDUSTRIES ASSOCIATION

BEFORE THE HOUSE SUBCOMMITTEE ON
COMMERCE, MANUFACTURING & TRADE

JUNE 27, 2013

Mr. Chairman and Members of the Committee, thank you for the opportunity to appear before you today. The Solar Energy Industries Association (SEIA) represents over 1,000 solar businesses operating within the United States, including leading U.S. solar manufacturers and exporters. Today, solar employs nearly 120,000 Americans at more than 5,600 companies, most of which are small businesses spread across the United States, making solar one of the fastest growing industries in America. My testimony today will focus on India's growing use of an industrial policy which discriminates against U.S. solar exports and, thereby, provides an unfair competitive advantage to India's domestic solar manufacturers.

With some of the best solar resources in the world, and the cost of solar continuing to decline, India's solar sector is posed for explosive growth, providing an important export opportunity for U.S. solar manufacturers. Indeed, over the past few years, U.S. solar panel manufacturers have contracted to supply hundreds of millions of dollars of exports to India. Importantly, most of these exports are comprised of U.S. solar panels based on "thin film" technology, a leading-edge U.S. technology with a global competitive advantage.

At the same time, however, India's solar policies have increasingly turned inward. In 2010, India adopted a local content requirement as part of the country's National Solar Mission. While we fully support India's desire to promote solar manufacturing, both as an economic development tool and a solution to climate change, India's government support measures must

be consistent with the country's international trade obligations. India's solar local content requirement, however, is a direct violation of those obligations.

One of the arguments we hear in support of the local content measure is that it is necessary to nurture the growth of a young industry, particularly in an environment of intense global competition. But while local content requirements may provide some protection for domestic manufacturers, such requirements also stifle innovation, limit a country's access to next generation technologies, and increase costs—not to mention the fact that local content requirements are explicitly prohibited by global trade rules.

Returning to the specifics of India's solar industrial policy, the National Solar Mission is divided into three phases. Under the first tranche of Phase I, India required that eligible projects based on crystalline silicon technology, versus thin film technology, utilize only solar panels manufactured in India. Thus, while U.S. solar cells could be exported to India for incorporation into panels that were then eligible for Solar Mission projects, U.S.-origin panels were barred from competing for Phase I projects.

For the second tranche of Phase I, India broadened the local content requirement to mandate that National Solar Mission projects use only crystalline silicon solar cells and panels manufactured in India. U.S. crystalline silicon solar cells, and now panels, are thus barred from competing for National Solar Mission projects—a significant lost opportunity for U.S. exports. Looking forward, we are concerned that India will expand its solar local content requirement yet again to cover not only crystalline silicon solar cells and panels but also U.S. solar panels utilizing thin film technology, effectively targeting hundreds of millions of dollars in U.S. solar panel exports. Our only hope is that the U.S. government's recent decision to initiate World

Trade Organization (WTO) dispute settlement proceedings against the local content requirement will eventually cause India to reverse course.

The U.S.-India WTO dispute follows on the heels of a recent WTO finding that Ontario, Canada's local content requirement for solar goods, which is substantially similar to India's, violated Canada's WTO obligations. In response, Canada has indicated that the solar program will be brought into compliance with the WTO decision, which we presume means that Canada will remove the local content provision. India should follow Canada's lead and, likewise, remove the local content provision from the National Solar Mission.

As important context, the U.S. government first tried to establish a collaborative dialogue with India regarding the local content requirement but was rebuffed. The U.S. WTO case was a last resort effort to get India to the table.

I want to again make clear that we support the overall objectives of India's National Solar Mission and its focus on growing a domestic solar manufacturing base. Notably, the U.S. WTO case challenges only one provision of the National Solar Mission—the local content requirement. The U.S. challenge does not threaten the National Solar Mission itself. Indeed, not all government support measures violate global trade rules and there are a variety of measures India could adopt as alternatives to the local content requirement. There is, however, no list, whether formal or informal, of WTO-consistent government support programs which countries could turn to for guidance.

Industry and governments, thus, have an important opportunity to work together and proactively develop such a list with the shared objective of expanding solar energy around the world free from the restraints of unfair trade barriers. The U.S. solar industry has consistently

maintained that while litigation is an important part of the global trading system so too is collaboration. That concludes my remarks, I would be happy to answer any questions.

Mr. TERRY. And now the gentleman, Mr. Malpani, you are now recognized for 5 minutes.

STATEMENT OF ROHIT MALPANI

Mr. MALPANI. Thank you, Mr. Chairman, and good morning. My name is Rohit Malpani, and I am the Director of Policy and Analysis of Doctors Without Borders.

Mr. TERRY. Is your mic on?

Mr. MALPANI. Yes, it is. Doctors Without Borders and Medecins Sans Frontieres. MSF is an international medical humanitarian organization which provides impartial medical assistance to those affected by armed conflict, epidemics, exclusions from healthcare or natural disasters. Today, MSF carries out this work in more the 70 countries worldwide while raising awareness on neglected crises and advocating for improved medical tools and protocols.

As a medical treatment provider, MSF is able to speak about the relationship between intellectual property rules and access to medicines and about the role India has played in enabling millions access to lifesaving medicines.

In 2001, MSF faced what seemed like insurmountable barriers in meeting critical health needs in saving the lives of our patients. In particular, we faced an astronomical $10,000 per person per year price tag for lifesaving HIV medicines which barred treatment for millions and prevented us from being able to reach more than a very limited number of patients.

But is a solution was found in India. The country, free from having to grant patents on medicines until 2005, was able to manufacture low-cost quality generic medicines for a fraction of the existing price. Literally overnight the cost to treat someone with HIV fell by over 96 percent to $360 per patient per year. Generic competition has seen the cost fall even further. As a result, more than 9 million people worldwide now receive treatment for HIV, many of those from PEPFAR-funded programs.

India's role in this treatment scale-up has been and continues to be a critical one. As the pharmacy to the developing world and the biggest source of quality generic medicines, governments and donors such as the United States rely heavily on Indian generic medicines. Ninety-eight percent of the medicines used in American taxpayer funded treatment programs rely on low-cost generic medicines manufactured in India.

Today India is a full member of the World Trade Organization providing patent protection for medicines. Between 2005 and 2008, India granted over 2,000 patents for medicines and continues to grant patents today. These patents delay generic competition, which keeps costs high and places enormous burden on treatment providers such as MSF, Ministries of Health in low-income countries and donor governments, including the United States.

While India does reward genuine innovation with 20-year patents, it manages to strike a balance between providing intellectual property protection and having the flexibility to protect public health. This balance is possible as both the TRIPS agreement and the Doha Declaration on TRIPS and public health enshrines the right of WTO members to implement safeguards and flexibilities. One safeguard under TRIPS is the right of governments to define

strict patentability criteria. Governments have the right to define scope of patentability in a way that addresses the needs of their own citizens as long as they abide by international agreements.

The United States recently contributed to its own definition when the Supreme Court reaffirmed strict patentability criteria for gene patents. India has adopted a standard of pharmaceutical patenting that is stricter than in the United States or the European Union, which is in line with international trade rules. In rejecting one patent application by Novartis on assault of an already known substance, the Indian Supreme Court was legally validating the choice by the Indian Government that patents should only be granted when those products represent a genuine advance over older versions of medicines.

By contrast, the United States has decided to approve secondary patents for very obvious modifications of existing medicines which often delays generic competition and keeps prices high. This is a practice commonly called evergreening by which the drug industry extends their monopoly on drugs beyond the originalpatent's 20 years. Allowing companies to extend patent protection and keep prices high is expensive for U.S. consumers and the U.S. Government.

A second legally recognized safeguard to overcome barriers of affordable access is the right to issue compulsory licenses. The United States Government used compulsory licenses for medicines in the past and stated that it would look to them in the future, if necessary. In India, a compulsory license was granted in the interest of public health when the country was faced with a price tag for a cancer drug which kept it out of reach of 98 percent of those eligible for treatment. Granting a compulsory license reduced the price by 97 percent while recognizing the innovation behind the drug through the payment of a 7 percent royalty.

The U.S. Government continues to make adjustments to its patent system to achieve a better balance between rewarding innovation and providing for public health needs. It should allow other governments like India to do the same. The measures taken by the Indian Government do not undermine innovation but rather curtail excesses of the patent system and ensure that companies focus their energies on scientific and not legal innovation.

Governments around the world and U.S. assistance programs are straining under high costs for new medicines. In times of economic austerity, we should remember that high medicine prices are an issue of life and death for millions of people. Ensuring that balanced innovation systems make those medicines available to those who need the most is imperative.

Thank you again for the opportunity the provide testimony on this important topic.

Mr. TERRY. Thank you, Mr. Malpani. I appreciate your testimony.

[The prepared statement of Mr. Malpani follows:]

MEDECINS SANS FRONTIERES
DOCTORS WITHOUT BORDERS

Submission for the Record to the Hearing:

"A Tangle of Trade Barriers:

How India's Industrial Policy is Hurting U.S. Companies."

Washington, DC - June 27, 2013

By Rohit Malpani - Médecins Sans Frontières/Doctors without Borders

Thank you for giving me the opportunity to provide testimony on behalf of Doctors Without Borders, also known as Médecins Sans Frontières, or MSF. My name is Rohit Malpani and I am the Director of Policy and Analysis at MSF's Access Campaign.

MSF is an international independent medical humanitarian organization created by doctors and journalists in 1971. Today, MSF provides impartial medical assistance in more than 60 countries, aiding those whose very survival is threatened by armed conflict, disease epidemics, malnutrition, exclusion from health care, or natural disasters.

MSF also works to raise awareness and galvanize action towards neglected crises, to challenge inadequacies or abuse of the humanitarian aid system, and to advocate for improved medical tools and protocols.

At the time that MSF was awarded the Nobel Peace Prize in 1999, the organization and many other treatment providers faced what seemed insurmountable barriers in meeting the critical health needs and saving the lives of our patients, particularly relating to the astronomical US$10,000 per-person, per-year price-tag for HIV/AIDS medicines, but also relating to the lack of effective and affordable tools to combat malaria, tuberculosis and many other tropical diseases that are some of the biggest killers of our time. MSF therefore launched the Access Campaign to advocate, on behalf of our medical teams, for affordable access to, and for the development of, needed medicines, diagnostic tests and vaccines for patients in MSF programs and beyond.

Part of the Access Campaign's remit is to identify and challenge the political, legal and commercial barriers that stand in the way of access to affordable medicines and that inhibit innovation for patients in developing countries. MSF's Access Campaign staff has expertise on patents and intellectual property rights, one of the major causes of high drug prices, and also on new models for innovation that better respond to patient needs while ensuring affordable access for all in need.

Today, MSF has been asked to provide testimony on India's patent law. As a medical treatment provider, MSF is able to speak generally about the relationship between

intellectual property rules and access to medicines, and in particular about India's patent law. I will address these issues shortly.

But I also want to make clear that this hearing cannot help but delve into issues much larger than the IP environment in India.

Firstly, whether the current medical innovation system works, and for whom.

I already mentioned briefly that the medical innovation system doesn't work for our patients. But even cancer doctors in the US believe the patent system is not working for their patients: when a new drug cost $11,000 per month, twice as much as an existing drug that worked just as well, they refused to offer it to their patients.

Secondly, how governments can best balance private commercial interests and public health in their IP laws?

These are questions that Congress is grappling with on the domestic front right now, and the U.S. government continues to make adjustments to its patent law to find the right balance.

For example, the U.S. Supreme Court recently affirmed the validity of the U.S.'s strict patentability criteria around genes, setting limits on what is patentable and taking into account public health needs and the vital importance of competitive markets for medical products.

The White House, in its FY2014 budget, has proposed steps to limit so-called 'evergreening' – abusive practices used to extend intellectual property monopolies, keeping prices high for as long as possible. The Administration also recently

introduced a package of executive actions and legislative proposals to stop abuse of the patent system by curbing lawsuits by 'patent trolls'.

As Supreme Court Justice Clarence Thomas, writing for the court last week in the Myriad Genetics case, said: "As we have recognized before, patent protection strikes a delicate balance between creating incentives that lead to creation, invention, and discovery, and impeding the flow of information that might permit, indeed spur, invention."

The same balance that the United States continues to define is under careful consideration in India also.

MSF has had medical operations in India since 1999. MSF provides health services to neglected and marginalized populations in the states of Bihar and Chhattisgarh, the disputed region of Kashmir, remote villages on the border with Myanmar, as well as the enormous city of Mumbai. Our operations include primary health care and routine vaccinations, nutritional support for children and pregnant women, and screening and treatment for malaria, HIV/AIDS, visceral leishmaniasis and tuberculosis, including multidrug-resistant tuberculosis.

India is an important manufacturer and supplier of quality generic medicines for millions of people around the world. MSF is highly dependent on the availability of affordable high-quality medicines to provide medical care, as are many of the Ministries of Health with whom we work. Ninety-eight percent of PEPFAR's HIV drug purchases are generic medicines from India. In fact, we call India the 'pharmacy of the developing world.'

Let me share an example of how generic medicines produced in India have changed the treatment landscape of an important disease like HIV/AIDS. From the US$10,000 price tag to treat one person for HIV ten years ago, market competition among multiple generic manufacturers in India brought HIV medicine prices down by nearly 99%, to roughly $100 today for the World Health Organization's recommended first-line antiretroviral, or ARV, treatment.

Currently, more than 9 million people are alive and on ARV treatment in middle and low-income economies, thanks to affordable prices that enabled treatment scale-up on a large scale. But many more are still waiting for access, and we need to continue scaling up treatment.

The generous contributions of the U.S. government in the global fight against HIV/AIDS have been pivotal in bringing us to the point where we can, for the first time, talk about reversing the AIDS epidemic as a feasible policy objective. We welcome new ambitions and efforts on the part of the U.S. government to translate the new science - that HIV treatment is, in fact, prevention - into policies that will scale up access to treatment. But the ability to implement these policies is directly linked to the ability of treatment providers to access medicines at affordable prices. Affordable ARVs are critically important to PEPFAR, to the Global Fund, to MSF, and to many others.

Here's where the U.S. government's inconsistent policies on global health and international trade collide. While the U.S. runs PEPFAR and is the largest donor to Global Fund, the U.S. is also pursuing international trade policies that will make it

harder for countries to implement laws to promote market competition and to protect public health; it will be much harder for patients, governments, treatment providers like MSF and U.S.-donor supported programs to have access price-lowering generic drugs.

These policies don't just affect affordability - they also negatively affect innovation. Fixed-dose combination antiretrovirals, which combine multiple medicines into a single pill, make adhering to treatment easier for patients, and make it easier for treatment providers to scale up care to more people. But these were first developed by generic manufacturers in India: because India did not, at that time, grant patents on pharmaceuticals, the individual medicines weren't patented there, allowing them to be combined into one pill.

In 2005, India and other developing countries began granting pharmaceutical patents in accordance with TRIPS. India granted more than 2,000 pharmaceutical patents between 2005 and 2008, and the country continues to grant patents.

But as India prepared to change its legislation in order to do introduce patenting for pharmaceuticals, the World Health Organization and UNAIDS wrote to the Indian government to ask the country to safeguard its role as main supplier of affordable quality antiretroviral and other medicines used in the developing world, and to urge the country to use the existing international legal regulations to ensure the harm to access to affordable medicines would be limited.

Indeed, the WTO TRIPS agreement offers countries important policy and legal choices to limit the impact of the new obligations to grant patents, and to balance its

enforcement of IP policy with public health needs. The 2001 Doha Declaration, that both the U.S. and the Indian governments signed, reiterated the right to use legal tools, known as TRIPS flexibilities, to promote generic competition that saves lives. One of the most important policy choices that WTO member states can make is related to the use of these TRIPS flexibilities.

Two flexibilities in particular are worth examining here:

Compulsory Licenses

The first concerns compulsory licenses (CLs). CLs are a legally recognized means to overcome barriers in accessing affordable medicines under international trade rules.

The Indian Patent Office has had the possibility of using compulsory licenses for many years, but unlike the United States and others, had never used the tool until very recently. In March 2012, faced with a lack of access for Indian patients to a kidney and liver cancer treatment, the Indian government issued a compulsory license on German pharmaceutical company Bayer's patented drug sorafenib tosylate. Bayer appealed against the license but India's Intellectual Property Appellate Board (IPAB) in Chennai upheld the decision in 2013.

The compulsory license was granted to the generic company Natco for eight years - the cancer drug will remain patented in India (until 2020) - and against the payment of a royalty rate now fixed at seven percent.

MSF welcomed the decision as it will increase access to this specific medicine that Bayer had previously only made available to a small percentage of eligible patients (slightly above 2 percent). The Patent Controller concluded that price of Rs 280,000 per month (approximately US$5,500) was not "reasonably affordable." In the decision, Natco was required to make the drug available within India at a price of not more than Rs 8,800 (approximately US$175) for one month's treatment.

The decision by IPAB confirmed that the Indian government is able to use all means legally at its disposal, and in conformity with international trade rules, to check the abuse of patents and open up access to affordable versions of patented medicines. This potentially paves the way for compulsory licenses to be issued on other drugs, for example those patented in India and priced out of reach, to be produced by generic companies and sold at a fraction of the price. In our statement, we expressed the hope that, in the near future, compulsory licenses will be issued for the newest drugs to treat HIV and affordable generic versions will be available not only in India, but in the rest of the developing world. Indeed, MSF has started to switch HIV patients who develop drug resistance onto newer medicines, which are expensive. At our Mumbai clinic, a third-line drug like raltegravir is prohibitively priced at US$1,775 per person per year.

As the number of people living with HIV, tuberculosis or hepatitis grows, more people will need to be switched to newer, more expensive and more effective treatments; the availability of affordable generic medicines will be critical.

We urge the United States Government to acknowledge that many medicine prices are too high for developing country governments and patients, and to allow for mechanisms, in conformity with international trade rules, to be established that offer sustainable solutions for accessing life-saving medicines at affordable prices in developing countries.

Strict Patentability Criteria - The Novartis Case

The second key TRIPS flexibility concerns patentability criteria. In 2005, the Indian government set a higher patentability threshold to ensure that patents are only granted on new compounds by discouraging undeserving secondary and follow-on patents. This limits the practice of evergreening. In this regard, the Indian patent law has been leading the way on how to implement WTO TRIPS-compliant laws that prevent abusive patenting practices.

Patents allow companies to have a time-limited monopoly to impose high prices by preventing competition from others. This is the ultimate balance at the core of the patent system: in exchange for allowing society to benefit from access to the invention, the inventor is able to profit from it, for a limited duration, usually set at 20 years.

Yet patent-holding companies regularly pursue evergreening strategies to prolong their monopolies ever further, thus breaking that fundamental balance. One common evergreening practice is to obtain multiple patents on a single medicine. For example, after patenting a specific drug molecule, companies often seek

additional patents to cover one or more features of a medicine, including 'process', 'formulation', dosage, combination pills and new uses. As a result, a single medicine can be protected by a large number of secondary patents, each relating to a different aspect of the same medicine; if these patent filings are staggered over a period of years, the end result is that monopoly protection for that particular drug can extend well beyond the original 20 years. In the U.S., a recent study found that secondary patents add, on average, more than six years of patent protection for the drug.[1]

Another study identified 108 U.S. patents and patent applications filed by Abbott for lopinavir/ritonavir, an important second-line HIV/AIDS medicine that combines two existing drugs, lopinavir and ritonavir. These patents could be used to protect market exclusivity for until at least 2028, even though patents on the basic compounds expire by 2016.

However, India sought to prevent this practice. As part of a series of amendments to the India Patents Act to fulfill its WTO obligations and that took effect on January 1, 2005, the Parliament of India adopted Section 3(d). This statutory provision has been in force for more than eight years. Section 3(d) was a response to the concern that the introduction of pharmaceutical product patent protection in India would substantially inhibit the availability of medicines both at home and in developing countries abroad. Parliament thus sought to limit practices that might result in the granting of secondary and follow-on patents, used to evergreen or extend patent

[1] Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of "Secondary" Pharmaceutical Patents, Kapczynski A, Park C, Sampat B (2012) PLoS ONE 7(12): e49470. doi:10.1371/journal.pone.0049470

terms beyond 20 years. Section 3(d) requires that patents for new forms of known substances should only be granted if they show a significant enhancement in efficacy.

Yet this provision, although fully compliant with international trade rules, came under immediate attack. Having been denied a patent on a drug to treat leukemia in 2006, Swiss pharmaceutical company Novartis first took the Indian government to court over Section 3(d) because it wanted a more extensive granting of patent protection for its products than offered by Indian law. In a first case before the High Court in Chennai, Novartis claimed that the Act did not meet rules set down by the World Trade Organization and was in violation of the Indian constitution. Novartis lost this case in 2007, but launched a subsequent appeal before the Supreme Court in a bid to weaken the interpretation of the law and empty it of substance.

All of Novartis's claims were rejected by the Supreme Court in April 2013. What the Supreme Court did is not only to reject a patent application by Novartis on a salt form of imatinib, but to confirm that the Novartis had failed to satisfy the requirement of inventive step as provided in the Patent law.

It is important to note what the Supreme Court did not say. It did not say that a new form of known compound may never be patented. It left open the question whether enhanced efficacy refers narrowly to curative effect, or more broadly to improved safety profile and reduced toxicity.

MSF very much welcomed the decision of the Supreme Court as our patients and doctors have already benefited from Section 3(d). Several secondary and follow-on patents, on key medicines such as tenofovir prodrug (TDF) for example, have been rejected in India for failing to meet the requirement of inventive step as stipulated in Section 3(d). The applicability of Section 3(d) of India patent law has meant that affordable generic versions of some HIV medicines adapted for babies and children (such as nevirapine hemihydrate) could be produced, as well as combination pills that include more than one drug in the same pill (e.g. tenofovir disoproxil fumarate and emtricitabine), and medicines better able to tolerate the heat. The Supreme Court's decision now makes patents and high prices on the medicines that we desperately need less likely.

When it comes to saving lives, determining the right balance for governments to strike in deciding what deserves a patent and what does not is a complex matter. MSF supports the Indian government decision that patents should only be granted for innovations that have accomplished something significant in terms of curative and therapeutic effects.

The Indian Supreme Court affirmed that India has adopted a standard of pharmaceutical patenting that is stricter than that followed by the U.S. or the EU. Having a stricter inventive step is not only allowed by international law and the WTO TRIPS agreement, but it is not even unprecedented in the United States. The U.S. used to have stricter criteria for patentability however today, the U.S. Patent Office and Federal Circuit will approve patents for very minor modifications.

This impacts U.S. consumers and the U.S. government in that it allows the manufacturers to market and sell higher-priced patent-protected versions of their popular drugs. In contrast, the Indian government, supported by the Supreme Court, has decided that Indian consumers should only pay for expensive patented products when those products represent a genuine advance over older versions of medicines.

The U.S. government continues to make adjustments to its patent system to achieve better balance and it should allow other governments, like India, to follow their own paths.

Conclusions: access AND innovation

The Novartis verdict sends a message to pharmaceutical multinational corporations to focus research on new drugs, rather than on ways to evergreen their patents. But the complex relationship between patents and medical innovation deserves a closer look. Are patents and monopolies the only way to reward expensive innovation? Could other mechanisms be better placed to answer our medical needs?

Relying on patent monopolies to drive forward research and development (R&D) and innovation is fundamentally flawed for two reasons; first, it means that it R&D is predominantly driven by commercial rewards rather than global health priorities. This means that research is steered towards areas that are the most profitable, leaving fundamental medical needs—particularly those that disproportionately affect developing countries like neglected tropical diseases or tuberculosis — unaddressed.

New data from MSF and the Drugs for Neglected Diseases *initiative,* a product development partnership co-founded by MSF and which focuses on developing treatments for diseases neglected by the market, shows that between 2000 and 2011, only 3.4% of drugs approved were indicated for neglected diseases while these disease represent 10.5% of the global burden. Of these 29 drugs, only 4 were new chemical entities (NCEs). The future is equally troubling: only 1.4% of a total of nearly 150,000 registered clinical trials were focused on neglected diseases, with very few of these trials for NCEs.

The second flaw is the inevitably high cost of the newer drugs, which are often priced out of reach of developing countries, and are increasingly becoming unaffordable in wealthy countries as well. As we have seen, high medicine prices are an issue of life and death for millions of people. In times of economic austerity when we learn with concern about possible budget cuts to PEPFAR, one of the most important US health programs, we should not only learn from the past - how HIV treatment was scaled up to more than 9 million - but we should continue looking for new ways to provide for the many still waiting, including the 25 million individuals that need urgent access to HIV/AIDS treatment.

We look to the U.S. Government to allow for mechanisms, in conformity with international trade rules, that offer sustainable solutions for accessing life-saving medicines at affordable prices in developing countries.

We also need to secure medical innovation that answers to the medical needs MSF sees in its medical programs.

Research and development is an expensive and risky process, and someone does need to pay. But how much does medical innovation actually cost? There is a commonly held misconception that the cost to develop a new drug is $1 billion or more. This number is usually mentioned by PhARMA representatives, including in Congressional testimonies. Andrew Witty, CEO of GlaxoSmithKline, recently called this $1 billion price tag, "one of the great myths of the industry."

It is difficult to determine what the research and development costs are for a given drug. Pharmaceutical companies keep this information confidential. But some have estimated that the cost for drug development is closer to hundreds of millions of dollars. What is well known is that companies invest much more on promotional and marketing practices than in research and development.

The current innovation system is failing too many. At MSF we believe the world needs to move towards a new framework for R&D that considers the specific needs of patients upfront, at the start of the innovation process; breaks the link between the cost of R&D and the price of products; ensures that the fruits of innovation are accessible and affordable; and moves beyond the ad hoc patchwork of limited efforts seen so far, transforming these individual successes into a sustainable R&D framework based on clear needs and agreed priorities. There are important conversations at the World Health Organizations on these new models for

innovation that the U.S. government and Members of Congress should strongly support and engage.

I want to finish this testimony by thanking you again for this opportunity.

Submission for the Record to the Hearing:

"A Tangle of Trade Barriers:

How India's Industrial Policy is Hurting U.S. Companies."

Washington, DC - June 27, 2013

By Rohit Malpani - Médecins Sans Frontières/Doctors without Borders

- MSF is an international independent medical humanitarian organization which provides impartial medical assistance in nearly 70 countries.
- As a medical treatment provider, MSF is able to speak generally about the relationship between intellectual property rules and access to medicines, and in particular about India's patent law.
- Critical questions that also need to be addressed include
    - Firstly, whether the current medical innovation system works, and for whom.
    - Secondly, how governments can best balance private commercial interests and public health in their IP laws?
- India plays a vital role as manufacturer and supplier of quality generic medicines for millions of people around the world. Generic competition and medicines from India have brought the price of antiretroviral medicines down by roughly 99%, allowing over 9 million people to be on HIV treatment today. Ninety-eight percent of PEPFAR's HIV drug purchases are generic medicines from India, known as the 'pharmacy of the developing world.'

- U.S. government policies on global health, through PEPFAR, are thus inconsistent with U.S. international trade policies, which negatively affect affordability of medicines.
- In 2005, India began granting pharmaceutical patents in accordance with TRIPS, granting more than 2,000 pharmaceutical patents in the three years after to 2008, and continues to grant patents.
- WTO TRIPS agreement offers **all** countries important policy and legal choices – known as TRIPS flexibilities – to balance enforcement of IP policy with public health needs. India has put in place legally sanctioned safeguards that prevent abusive patenting, as part of flexibilities granted in WTO TRIPS agreement in 2001.
- One such flexibility is to set a higher patentability threshold to ensure that patents are only granted on new compounds, by discouraging undeserving secondary and follow-on patents. This limits the practice of evergreening. In the Novartis Case, the Indian Supreme Court recently affirmed India's right to adopt a standard of pharmaceutical patenting that is stricter than that followed by the U.S. or the European Union countries.
- A second flexibility is the granting of compulsory licenses (CL), which are another legally recognized means to overcome barriers in accessing affordable medicines under international trade rules. When faced with a lack of access for Indian patients to a patented kidney and liver cancer treatment, the Indian Intellectual Property Appelate Board (IPAB) recently issued a CL, and the price

dropped by 97 percent, while the innovator company received a seven percent royalty.

- The U.S. government continues to make adjustments to its patent system to achieve better balance and it should allow other governments, like India, to follow their own paths.
- We look to the U.S. Government to allow for mechanisms, in conformity with international trade rules, that offer sustainable solutions for accessing life-saving medicines at affordable prices in developing countries.
- Relying on patent monopolies to drive forward R&D and innovation is fundamentally flawed for two reasons;
    - first, R&D is predominantly driven by commercial rewards rather than global health priorities. This means diseases that disproportionately affect developing countries are neglected.
    - Second, an inevitable consequence is the high cost of new medicines, which are priced out of reach of developing countries, and are increasingly becoming unaffordable in countries like the U.S.
- The current innovation system is failing too many. MSF believes the world needs to move towards a new framework for R&D that
    - considers the specific needs of patients upfront,
    - breaks the link between the cost of R&D and the price of products;
    - ensures that the fruits of innovation are accessible and affordable;

- There are important conversations at the World Health Organizations on these new models for innovation that the U.S. government and Members of Congress should strongly support and engage.

Mr. TERRY. And for the record, unanimous consent to submit a letter from the Ambassador of India in response to several Members objecting to the patent and trademark issues. Hearing none, we will submit that for the record. And also a letter from Advancing Global Technologies, TIA, to me and Jan Schakowsky, our letter from Grant Siefert.

Any objections? None heard. So ordered.

[The information appears at the conclusion of the hearing.]

Mr. TERRY. And you have another one. All right. A little business before we have questions.

Mr. MCNERNEY. I have two documents to submit for the record.

Mr. TERRY. All right. Go ahead.

Mr. MCNERNEY. Mr. Chairman, I have two documents to submit for the record, one from the California Healthcare Institute, and this one, I think, is submitted to the House committee on the Tangle of Trade Barriers: How India's Industrial Policy is Hurting U.S. Companies.

Mr. TERRY. With no objection heard, so ordered.

Mr. MCNERNEY. OK. The second one is by the Public Citizen, "India's Patent System Plays By WTO Rules and Supports Global Health." I would like to submit this for the record.

Mr. TERRY. Hearing no objection, so ordered.

[The information appears at the conclusion of the hearing.]

Mr. TERRY. All right. Now the fun. Question, and no pun intended. Well, actually it is. I am going to ask a fairly generic question to the panel, but obviously with the practices of India in the last couple of years and compulsory licensing practices and seeming court orders to usurp patents or deny a patent, this seems to be an economic development policy issued by the state.

Now, how political do you think these protectionist measures are? Is India continuing to head in even a deeper protectionist direction or does the government simply flow with the trade winds, so to speak. And if you can keep it within about 45 seconds per answer, I want to go straight down the panel, and we will start with you, Ms. Dempsey.

Ms. DEMPSEY. Thank you, Mr. Chairman. From our perspective, what we are seeing in India today is a reversal, of course, from the liberalization they were inching along in, and it is a broad policy across a bunch of different sectors. Intellectual property is a key piece of it. Localization is another piece. But it is a move to shut their economy, to try to grow their economy at the expense of ours in the United States and other foreign countries.

Mr. ELLIOT. I would agree with Linda's statement. I would add, I think that there are mixed signals that often come out of the political hierarchy there. The President has made some very positive statements, but clearly the direction of the company is going in another direction. So, it is a situation where quite often the rhetoric is very different to what is happening in the real world, and the real world seems to suggest that India is heading in a very wrong direction.

Mr. WALDRON. I would say, for the pharmaceutical sector, that there most definitely is a protectionist bent towards protecting their own industries. In fact, when the patent law was implemented in 2005, there were explicit statements about protecting

and designing a law to protect local interests and the ability for those companies to maintain their export markets. So there definitely is a concerted policy, and even looking at the Supreme Court decision on the Gleevec decision, it is clearly within there that the protection of export markets is intended.

Mr. HOFFMAN. To your initial point, Mr. Chairman, you can't escape the political dynamic that is currently going on in India. You have a country that is within one year of elections at the national level and elections that are considered to be very tight. That said, I agree with my fellow panelists that the trend is more in the direction of protectionism, while there is certainly a bit of discussion of sorts that is going on internally with the Indian Government. I think what raises the level of concern is that currently heading the government was the architect of the opening of the government of India, the Prime Minister saying when he ran the Finance Ministry in 1991, essentially, you know, opened the doors not just for the overall economy but for the IT industry. So when you have someone of that stature who has a free market background, yet various departments and agencies are pursuing protectionist measures that give a lot of us here cause for concern.

Mr. TERRY. OK.

Mr. SMIRNOW. I think India, first and foremost, sees the role long-term——

Mr. TERRY. The microphone.

Mr. SMIRNOW. I think India sees, as a lot of countries do, the long-term opportunity of solar energy, particularly as a job creator, and so that really is their focus.

The current global environment for solar, we have massive overcapacity, and so it is difficult for young companies and a young industry, which is India is trying to grow to compete in that environment of intense global competition. So that really, I think, is the motivator for them to utilize the local content requirement to protect this young industry, but it is the wrong mechanism and there are a variety of other solutions they could turn to that would be WTO consistent.

Mr. TERRY. All right. Mr. Malpani.

Mr. MALPANI. We know that the TRIPS agreement, under which these rules are formulated, specifically create exceptions for public health and public interest, and we think that is the reason why India is using their rights and flexibilities.

We heard a statistic that there is a 500-million person market in India today for various technologies. There is another 500 million people in India without clean water and electricity today as well as millions of other people in the developing world.

The other thing to remember is the concept of separation of powers, which is so sacred in the United States. These decisions at the Patent Office and at the Indian Supreme Court are done by the judiciary, not by the executive or legislative branch, and I think India maintains that same separation of powers as United States has with its patent decisions.

Mr. TERRY. Well, that concludes my time. And I recognize the gentleman from California, Mr. McNerney, for his 5 minutes of questions.

Mr. MCNERNEY. Thank you, Mr. Chairman. This is a very important hearing. As we know, the United States, we take a lot of pride in our intellectual properties and our innovation. And we want to see that take place in India within a framework that benefits both countries. And we don't seem to be hearing that that is what is going on there. So I appreciate the testimony that we have heard this morning.

But I would like to sort of make one point first. Mr. Malpani, I was going to ask you to explain evergreening, but you did a pretty good job in your testimony. I just want to ask is that one instance of a progressive policy adopted by India which is putting it ahead of many of the other countries. Is that one example then?

Mr. MALPANI. India's policy on evergreening is one actually that has also been adopted by other countries, sometimes in parallel to India and sometimes afterwards. This is a flexibility that is fully recognized under the TRIPS agreements. Actually, the United States itself had a more strict patentability standard in the past, which has been loosened up over the last few decades, and which has led to this profusion of secondary patents that delay generic competition far beyond 20 years. This, in our opinion, has been done specifically both to protect the public interest, to ensure that the patent term does not exceed 20 years except for genuine innovation, and it is also we think to encourage real innovation instead of simply trying to encourage legal innovation on behalf of drug companies.

There is a study in the United States which shows that secondary patenting and evergreening leads to an additional 6 years of patent protection for medicines in this country, which thereby creates higher costs for consumers and for the health care system.

Mr. MCNERNEY. Thank you. Mr. Smirnow, I am a very big proponent of clean energy technology. Let me ask are there Indian trade rules that target the United States specifically?

Mr. SMIRNOW. The local content provision that I am concerned about does not target the United States specifically. It is any import into India of the technology at issue. Though India has initiated an anti-dumping duty case that includes the United States. That case is in the preliminary stage. It targets the United States, China, Taiwan, and Malaysia. So that would be one example where there are some activities that are targeting the United States.

Mr. MCNERNEY. Can we work collaboratively with them to help resolve those barriers, or is that something that they are pretty firm in right now?

Mr. SMIRNOW. Yes, I hope so. And I think there is an opportunity and a responsibility of industry to build some bridges with India in the renewable space. Over the past couple years, SEIA has been working with the leading solar trade associations in Europe and Asia to find ways to collaborate. We haven't yet built those bridges with India, and we need to. And I think I commit today to reach out to the Indian solar industry and start building those bridges. I also think there is an opportunity to inject trade into some of these collaborative efforts that the State Department, Department of Energy are engaged in right now.

Mr. MCNERNEY. Thank you. Mr. Hoffman, it is good to see you here in the committee. What specific recommendations would you

have for India so that it can build its electronic and telecommunication equipment production capabilities without resorting to these localization practices?

Mr. HOFFMAN. Well, first and foremost, do what works. Rely on the market-based incentives that have created an extraordinary IT industry all over India. That is first. Second, it should have joined the ITA expansion talks. They are at the end stages. They could still potentially join and sign the ITA expansion. That was extraordinarily helpful to provide the IT industry in India with duty-free treatment of products that enabled them to build the infrastructure that they needed to succeed. As a number of my panelists know, manufacturing is very IT-enabled these days. So you can use those same building blocks in ITA expansion. And so we are hopeful that perhaps they will ultimately join with the expanded ITA.

Mr. MCNERNEY. It sounds like there are steps that they are aware of that will help them actually improve their economy without resorting to these localization practices.

Mr. HOFFMAN. And I do want to make one concluding point, Congressman. Right now, I mean you saw—I waved it around, but you saw the article in the Economic Times of India, I can certainly provide it to the staff to distribute to the members of the subcommittee, but they are on the cusp of taking their forced electronics manufacturing policy into the private sector. And we would strongly urge them to basically, you know, stand pat. We believe to go further forward would be very disruptive to their own economy, to our own, and to other governments and industries around the world. So they literally have their toes on the line. We know that there are discussions going on internally within the government not just in terms of where to put it through with the private sector, but there is also talk about applying it to software. So we hope that they will keep those toes on the line and not proceed forward.

Thank you.

Mr. MCNERNEY. Thank you.

Mr. TERRY. Thank you. The gentleman's time has expired. And the chair recognizes the full committee chair, Mr. Upton, for 5 minutes or as long as he wants.

Mr. UPTON. Five minutes will be good. Thank you, Mr. Chairman. I appreciate everyone's testimony this morning. I just want to say when I first learned of this issue just a few short weeks ago, from Pfizer, the largest employer in my district, it has been amazing how many other companies walking to vote, doing a variety of different things that we do, a number of different companies have come up and shared with me their exact same story about trouble with India. And Mr. Waldron, I also want to thank you for your kind words in regard to the committee's work on enacting PDUFA last year. Every member of this committee, Republican and Democrat, was a strong supporter. And we were able to carry that ball down the field and get it through the Senate and to the President.

The question that I have, Pfizer, you have been there some 60 years now in India, Mr. Waldron. What is different now? What is happening that is different now from the landscape prior to the creation of their IP regime? Can you walk us through some of the things that have happened?

Mr. WALDRON. Yes. In the early days we were primarily a consumer health company in India. Our biggest products were vitamins and cough syrups. With the change in the law, it was expected there would be the support mechanism of IP to help us introduce innovative medicines into the market there.

Mr. UPTON. And that lured you in more, right? I mean that lured more investment into India?

Mr. WALDRON. Yes. To launch a new drug into a market is a costly adventure. And you do have to provide medical education. It is an advance for a market like India to receive almost immediately the benefits of a new innovative medicine from the innovator. So this is of great value and importance to patients in India. And I couldn't stress more that having that support mechanism in place does allow us to do what we do best.

Mr. UPTON. Now, in your testimony, and I was late coming to the hearing for a variety of other important reasons, but you indicated that since early 2012 India's policies and actions have undermined patent rights for at least nine innovative medicines. Many of these medicines have received patent protection in most countries across the world, suggesting that India is an outlier in recognizing and enforcing patent rights. This is not only creating significant uncertainty in the market, but it also undermines our ability to compete fairly in India and our willingness to invest there.

Are you actually considering reductions in investment in India? What is the landscape that you are looking at in the future as it relates to that?

Mr. WALDRON. I think it is too early to comment on what decisions may or may not be made going forward. I think it is going to be a matter of whether one can continue to do and introduce those products without a support mechanism to do it. I think we have to see, and time will tell, whether the environment becomes so hostile that you just have to retreat.

Mr. UPTON. Now, the argument on the other side from the Indian Government, they have repeatedly stated that they have a complete ecosystem supporting a well settled, stable, robust intellectual property regime. Specifically, they go on to say that multinational companies like Pfizer have been granted many patents in India. How do you respond to that claim?

Mr. WALDRON. Well, the Patent Office has been very active since the adoption of the patent law in 2005 in issuing patents. But it is really important to note that the issuance of a patent is only significant if a right actually attaches to that piece of paper. What we complain of at this point is that notwithstanding the existence of these documents that are issued from the administrative agency, when you try to enforce or try to give them meaning they sort of fail in the breach. A lot of the filings that happen in India, or at least worldwide, are very early stage scientific things. So a lot of the things that you see pending or have been allowed are probably things that are in the phase one, phase two stage, and have not yet reached the commercial stage, but I would say enforcement in the breach is where it really matters when you are talking about IP rights.

Mr. UPTON. Have you had any help from the administration in terms of the Trade Rep or any of the Federal agencies here in terms of complaints that have gone forward?

Mr. WALDRON. We have been speaking with USTR and the administration, and we are very hopeful that this issue has been raised during Secretary Kerry's visit to India, and hopefully that this dialogue will continue. This is very important that these issues be raised in bilateral discussions with India so that they understand that we really are serious about this. So I expect going forward that we will at least have this. And I have seen to date that the issue has gotten some traction.

Mr. UPTON. Well, hopefully this hearing will elevate the cause as well.

I yield back. Thank you.

Mr. TERRY. Thank you. And now the chair recognizes the full committee ranking member, Mr. Waxman.

Mr. WAXMAN. Thank you, Mr. Chairman. In November 2011, Secretary of State Hillary Clinton said that if we make smart investments based on sound science and a shared global responsibility we can save millions of lives and achieve a goal once considered unthinkable, an AIDS-free generation. We have made remarkable progress toward that goal. The United States, through its PEPFAR program, has helped hundreds of thousands of people each year avoid contracting HIV, and now provides direct support for the antiretroviral treatment of more than 5 million people with HIV. That is three times the number that were supported as recently as 2008. But there is still a long way to go.

In India, the focus of today's hearing, there are more than 2 million people infected with HIV. Worldwide, there are 2.5 million new HIV infections a year. And in this difficult spending environment, even the budget for PEPFAR was recently cut. In these circumstances, if we are to achieve our goals, low cost medicines must play an essential role.

Mr. Malpani, what are the provisions of the TRIPS agreement that permit countries certain flexibilities on intellectual property rights, and what purpose do they serve? And how are these reinforced in the Doha Declaration?

Mr. MALPANI. Thank you for the question. Just to reiterate that treatment is prevention for HIV today. It leads basically to 100 percent reduction in the transmission of the virus. And for the first time in history, we have a chance at defeating HIV. The TRIPS agreement and the flexibilities included in the TRIPS agreement can play an important role in ensuring affordable generic medicines. As I mentioned in my testimony, the scope of patentability clause in the TRIPS agreement allows countries and governments to define what is patentable or not so they can prevent evergreening and long terms of monopoly protection. There is also provisions around compulsory licensing which allow governments to exercise patents to allow the importation or production of generic medicines to bring down costs and to protect public health. There are also other provisions in the TRIPS agreement that allow the early working of drug patents to allow generics to enter the market when a patent expires. This is used in the United States, as well as parallel importation of medicines, which is not in the United

States, but which is used across much of the developed and developing world.

Mr. WAXMAN. The United States was among more than 140 countries to agree to the Doha Declaration, which clarified the circumstances under which countries may issue a compulsory license on a patent.

Can you talk specifically about India's compulsory license on the Bayer drug Nexavar and the Supreme Court decision regarding the patentability standards for the Novartis drug Gleevec? And in your opinion is India acting within its obligations under the TRIPS agreement?

Mr. MALPANI. Yes. We do believe that in both situations the government has acted within the scope of the TRIPS agreement. With respect to the decision with Novartis, the issue at hand is whether or not the measure that India has used to strike down the patent on imatimib mesylate is under the TRIPS agreement. And we believe it does. It is part of the three-part test under the TRIPS agreement for defining what is inventive. It is not an additional provision under the three-part test of the TRIPS agreement. It specifies what is an inventive medicine under TRIPS.

Similarly with respect to compulsory licensing, we believe that India used compulsory licensing under public health grounds to ensure an affordable price for the medicine. And in the order issued by the Indian Patent Appeals Board, it specifically mentioned that public health and affordability of the medicine was grounds for the compulsory license.

Mr. WAXMAN. As I mentioned at the beginning of my questioning, the U.S. has set a goal for an AIDS-free generation. Can you talk about the possibility of countries expanding the scope of patentability for certain drugs or establishing TRIPS-plus patent standards and how that could affect our ability to reach our goal?

Mr. MALPANI. We are enormously concerned with many measures that occur right now, especially the United States, for instance, which is negotiating the Trans-Pacific Partnership, which is seeking to go constrain the ability of governments to both oppose patents through an oppositional process, as well as broadening the definition of scope of patentability so that the patent system ends up importing many of the frivolous patents that are often granted in the United States and the European Union. We also see a lot of bilateral pressure upon governments not to impose a strict standard of patentability to ensure that only high value patents that actually reward true innovation are being granted. So it is not only in the bilateral relationships, it is also through free trade agreements and through other measures which is leading to a broadening of the scope of patentability and leading to longer patent terms.

Mr. WAXMAN. Most PEPFAR recipients currently receive first line antiretrovirals, which are typically generic drugs, and off patent, but after taking these drugs for some time, many patients develop drug resistance, requiring second line antiretrovirals, which cost the U.S. Government 135 percent more because many are brand name and on patent.

You mentioned in your testimony about Abbott's application for a secondary patent for an important second line antiretroviral

drug. Can you comment generally about how secondary patents on some of these brand name drugs could affect PEPFAR's ability to deliver affordable antiretrovirals to individuals who develop drug resistance in first line drugs?

Mr. MALPANI. Yes. We are facing what is known as a treatment time bomb today. All AIDS patients must switch to new second and third line medicines to continue treatments. And because these medicines are under patent, including in India and other countries, the costs are skyrocketing for our patients also. For one key third line drug produced by Merck, we have to pay $1,800 per patient, more than 10 times the cost of first line medicines.

Mr. WAXMAN. Thank you, Mr. Chairman.

Mr. TERRY. Thank you, Mr. Waxman. And now recognize for 5 minutes the vice chair of the subcommittee, Mr. Lance.

Mr. LANCE. Thank you, Mr. Chairman. And I apologize to the panel for being in and out this morning. There are several hearings this morning of this full committee. And I want to assure every member of the panel that I think this is an incredibly important issue.

Mr. Waldron, Dr. Waldron, Counselor Waldron, many titles, you have testified that 80 percent of the users of your drug Sutent receive a complete or partial subsidy. It is my understanding that one of the arguments of the Indian Government in ordering a compulsory license is that drugs are needed for public health because the drugs are otherwise out of reach for Indian patients. Isn't it true, however, that Indian-made generics are priced out of range for most of the population? And so therefore how is it in the interests of public health to manufacture a drug that is cost prohibitive when 80 percent of the Indian drug consumers are already receiving a drug from the patent holder either free or at a steep discount?

Mr. WALDRON. Yes. Thank you. Thank you, Vice Chairman, for that question. It is one of the misperceptions that increased generic entry means more access to medicines. And that is part of the problem that is facing us in this debate. From 1972 to 2005, there were no patents protecting innovative compounds in India, yet only 20 percent of the population in India had access to medicines. Eighty percent did not. Even now that figure is better than in the period—I think it is about 30 percent now have access to medicines, versus an earlier period where there were no patent protections. So the connection between patent protection and access to medicine is somewhat tenuous at best. We really have to look at mechanisms that do increase access to medicines. I mean we agree with the ultimate objectives of MSF——

Mr. LANCE. Of course. As do we all.

Mr. WALDRON [continuing]. And PEPFAR. And these are objectives that we all want to work towards. But I think the difference is in the mechanisms to get there. Compulsory licensing and abrogating the IP system really doesn't seem to be—have a linear relationship between that and increased access to medicines. Or at least that hasn't been shown anywhere in which this has been exercised.

Mr. LANCE. Thank you. I would be interested in your opinion regarding the Supreme Court's decision, the Indian Supreme Court

decision, in the Novartis Gleevec case. As I understand your testimony, you believe that it is inconsistent with the Indian obligations under the WTO agreement on Trade-Related Aspects of Intellectual Property Rights, TRIPS. Could you explain the position of Pfizer regarding that issue? And I understand there may be a disagreement on the panel. I would be interested in your position.

Mr. WALDRON. Yes. When you speak about drug development, I mean you have the development of an active pharmaceutical ingredient and then you have subsequent innovation that occurs after the identification of that active ingredient. Sometimes the active ingredient is not bioavailable. You give it to a patient, it goes right through their system. You want that incremental innovation that occurs after that to make sure that you are getting optimal exposure to the patient of the drug. That is called pharmaceutical sciences. It has been practiced by pharmacists for centuries, compounding and making drugs that actually take that active ingredient and make it available to patients. That is innovation. Pharmaceutical sciences is a branch of science which pretty much literally has been written out of the Indian patent law and proscribed from patentability. And that is really something that should be part of the law, to encourage the kind of innovation that you want and makes those drugs better available to patients.

Mr. LANCE. From my perspective you have hit right on the key, and I appreciate your testimony in that regard.

India has been praised for improving access to medicines in parts of the developing world. It is my understanding that India raises more money taxing medicines than it actually spends on medicines for its own people. Mr. Waldron or perhaps others on the panel—I start with Mr. Waldron—can you describe some of the access programs that your industry has implemented to help Indian patients regarding innovative medicines?

Mr. WALDRON. I think one of my fellow panelists described the Novartis access program.

Mr. LANCE. Yes.

Mr. WALDRON. I have described our access program. But most all of the industry has implemented an access program in one form or another to make these drugs available to patients. The problem in India is that there is no counter-facing public health system in which to interact with. There is no government payer. So a lot of this has to be done at the private level or at direct interactions with clinics. So it is a very difficult dynamic than what we see in the United States, where we have a government payer versus another situation. So most of the industry has tried to do its best in these circumstances, but when you are not dealing with a system that treats all of the patients, the access to medicines issue become becomes an access to health care issue, which is a completely different thing.

Mr. LANCE. Thank you. My time has expired. Thank you very much.

Mr. TERRY. The gentleman's time has expired. The chair recognizes the gentleman from Utah.

Mr. MATHESON. Thank you, Mr. Chairman. I appreciate the panel participating today.

Mr. Waldron, from listening to today's testimony, it appears India is using its intellectual property law to build up their domestic industries at the expense of U.S. innovators.

Can you elaborate on how these types of policies threaten to harm your specific industry if left unchallenged?

Mr. WALDRON. What is happening in India is being looked at very carefully by other countries. It is a portions and pieces of what has been implemented in the Indian patent law has been adopted by Argentina, the Philippines, it is being looked at in Turkey. In fact, in some of the more developed countries they are actually looking at—more actively at anti-IP-type measures. This is very distressing for the point that it is the boom that has given the benefits to our economies. So we have to be very careful about counteracting anti-IP sort of contagion and spillover from India. And I think unless we are willing to look at the crucible of the activity that is happening in India and sort of draw a line and say this is unacceptable at some point, it is going to be seen as permissible by the Brazils and the South Africas and other countries to sort of take it upon themselves to implement measures, particularly if there is no downside to doing it. The biggest downside is the long term downside that it affects the innovative economy. It would be very shortsighted if we really were not to sort of take a stand at this point and protect the innovative environment which is protected by intellectual property.

Mr. MATHESON. And you may not be able to answer this question, but to the extent that you see potential spillover into other countries to adopt these same policies, do you have a sense of how soon that could be presenting itself to us where we are having a hearing again, that Chairman Terry is going to call a hearing and talk about instead of India it will be another country? Where is this happening so quickly?

Mr. WALDRON. I think we are seeing it in real time. As I mentioned, Argentina has adopted patentability restrictions or guidelines that affect it. The Philippines have as well. The Brazilians are looking very carefully at different mechanisms. So we are seeing sort of a very concerted international effort on this. And I think it is really time that we sort of make a stand on the value of IP. And that is what we should do as a country because we are innovators, we export innovation. And that is really so critical to our economy.

Mr. MATHESON. I appreciate that. Mr. Hoffman, in your testimony you suggest that resolving issues like India's preferential market access initiative through the World Trade Organization would not be ideal for industry entrepreneurs. Is that a fair characterization, first of all?

Mr. HOFFMAN. It is certainly not ideal, largely because——

Mr. MATHESON. Can you just expand on why you don't think that is the right way to go in your opinion?

Mr. HOFFMAN. Well, it is more of a when all else fails kind of a recommendation. And the simple reason why is that it takes years to resolve. And in our industry, 2 or 3 years are three iPhones and 20 versions of Angry Birds. I mean innovation just keeps moving along. And so we hope, again this is one of those situations where when you have a mutually advantageous situation

where both countries are innovating like they are doing, listening to Mr. Waldron, Dr. Waldron, Counselor Waldron, I have to—hearing what he is saying in terms that we are an innovation economy, you want to export innovation. India has progressively moved up the value chain when it comes to information technology. And they are exporting more and more. Why would you risk that? By not only locking yourselves out, but the contagion effect that Mr. Waldron just talked about certainly applies in our case as well. So we hope that given, again, the mutual understanding that we both have about the benefits of innovation entrepreneurialism we can resolve this short of giving—handing this over to the trade lawyers in Geneva.

Mr. MATHESON. With that, Mr. Chairman, I just suggest that this potential of this spreading to other countries just highlights the importance of this hearing even more. And with that, I will yield back.

Mr. TERRY. Good point. The chair now recognizes Mr. Guthrie.

Mr. GUTHRIE. Thank you, Mr. Chairman. I appreciate that. I appreciate everybody being here. Ms. Dempsey, reading through your testimony, we have all talked about the range of problems with India. You reference in your testimony the bilateral investment treaty and negotiations that are on hold now because of India's recent actions. What would you like to see happen now that could get these negotiations started again? What would you like to see?

Ms. DEMPSEY. Sure thing. We at the NAM have been strong supporters of bilateral investment treaties as ways to grow reciprocal investment, investment that comes into the United States that benefits manufacturing and other economic activity here, and also broadens our relationship with those other countries. If India were prepared to agree to, to negotiate the type of high level BIT provisions that were recently reviewed by this administration and put out in April of 2012 that include market access provisions, basic provisions from our own Constitution, things like takings and due process and nondiscrimination, including provisions I think that would get at many of the property rights and forced localization issues that we are seeing, as well as high level enforcement mechanisms, then we would see that the Indian Government is serious about moving forward and growing the U.S.-Indian relationship. As I understand it at the moment, the Indians, we started these negotiations back in 2008. The U.S. took some time to review its model under this administration. And now the Indians have said, well, we are reviewing our model, a model that was already relatively weak compared to the United States system. If India is not ready to negotiate this type of high level treaty, there are a lot of other countries in the world and Africa and parts of Asia that would be very interested in negotiating this. We have these types of treaty arrangements or through our trade agreements with about 60 other countries. And they really are a win-win for both sides.

Mr. GUTHRIE. Thanks. And Mr. Hoffman said in your testimony, I believe, and I quote, "That India's policies that are certain to reverse its past successes as an emerging economic power." And is that what you are leading to? I mean is it just foreign direct investment you think they will lose, or what is the nature of that? Or add to that quote, I guess.

Mr. HOFFMAN. Well, we are already seeing it. We are already seeing a significant decline in foreign direct investment. I think there is a genuine concern about the direction where the country is going. But meanwhile, you can't just view India in a vacuum. You have to understand that a lot of other countries in the region are following the same playbook that India used in the 1990s, and they are developing an educated workforce. They are actually encouraging companies that have invested in India to expand in those countries, and they are essentially trying to adopt the global innovation supply chain that India developed. You take a restrictionist approach, you are essentially turning your back on the very things that you helped to create, and literally handing it to your competitors in the region.

Mr. GUTHRIE. This is open to the panel. Has India replaced China as the country presenting the most challenging environment to intellectual property? India has replaced China or are they both very serious? I know that came from your testimony, Mr. Elliot. Thanks.

Mr. ELLIOT. I will take a stab at that. Look, due to the size and scope of China's market, I.P. theft will continue to be a huge problem. We will continue to need to work with China and the Chinese Government for some time. That said, there are a number of examples where the Chinese Government appears to have been responsive to issues raised with them. And in some areas, they are certainly moving in the right direction.

Two points to be made about India I think are that firstly, there has been a steep decline with respect to the I.P. environment there over the last 18 months. So they are clearly heading in the wrong direction. The second point I would make, in referencing back to the international index that was released last year, the baseline is already low. They are already the lowest in the world when it comes to their I.P. environment. So the bar is low, and they are already heading further down. And that is the concern with respect to India.

Mr. GUTHRIE. Thanks. Our Founding Fathers put in the Constitution a robust patent. That is an enumerated power of Congress. Because I think what we have done in the last 226 years since our Constitution has been adopted has been phenomenal. And I think it is because we have had protection of intellectual property. And now that we are global, and you can invent it here and create it here and it happens and you lose it overseas, that is a problem with investment. And granted, there are issues with costs and trying to make sure that we get products to people that need them at the right price at the right time, which we need to focus on.

But thank you, and I yield back.

Mr. TERRY. The gentleman's time has expired. The chair now recognizes Mr. Olson of Texas.

Mr. OLSON. I thank the chair, and welcome to our witnesses. The topic of this hearing is very important to me. My district, Texas 22, is the most ethnically diverse district in America. And the Indo-American part of that diversity is the fastest growing part. If the Indo-American community in Texas 22 grows like it did between the census of 2000 and 2010, in the 2020 census they will be the

majority minority in Texas 22. They will be larger than the African American population, larger than the Hispanic American population, larger than the Anglo American population. They will be the largest. And Texas 22 is the only one in 435 congressional districts that has that blessing. But robust trade with India that complies with international standards is more important than ethnic diversity in my district of Texas. It is important for our national security. Looking at a map of the world, like I did last night, the U.S. is facing threats to our security from both sides of the ocean, Pacific side, the Atlantic side. If you could magically take a flight out of Reagan National and head due east, after you cross the Atlantic you would hit Morocco, then Algeria, Tunisia, Libya, Egypt, Saudi Arabia, Jordan, Lebanon, Syria, Iraq, Iran, Pakistan, Afghanistan, Bangladesh, Nepal, China, Thailand, and Myanmar. Now you are over the Pacific heading home. There are not a whole lot of friends on that route. In fact, most of those countries are dominated by radical Muslim governments that want to hurt America. There are two democracies on that flight path, Israel on the eastern Mediterranean Sea and India in the heart of Asia with a dominant position on the Indian Ocean. I have seen firsthand that dominant position because I deployed for 6 months to an island called Diego Garcia in 1994 in the dead center of the Indian Ocean. And while India is the world's largest democracy, she is still young at 66 years old, and going through some serious growing pains associated with individual freedoms and free market economies. When our country was 66, we were having some big problems that manifested themselves in a Civil War 20 years later. Our trade relationship with India has grown dramatically in the last 2 decades. American businesses need that huge market. And India needs us. And like all of you all, my blood boils when I hear that India is revoking and denying patents and granting compulsory licenses for cancer treatments, or adopting local content requirements, or the recent Chamber of Commerce study that ranked India's IP environment behind China and Russia. China? China can't spell IP if you spot them the I. As a nation, we stand with India like my dad did when I was growing up and I made his blood boil. He put his arm around me and showed me or pulled me where he would go to make sure with his fingers resting firmly on my shoulder just to inflict some pain if I diverted from the course we needed to go down. That is what we should do with the Indian Government. A real high level question here, and sorry for the time, but most of the discussions on trade policy with India occur in the executive branch. We talked about the Secretary of State going there, the Vice President, the Secretary of Energy went there recently. Is there a role for Congress? And most importantly, what can I do with my district to help get some grass roots? Because we have people in my district who have great strength, great pull. What can I do to help make sure we get India on the right path again?

All the way across the board. Start with you, Ms. Dempsey.

Ms. DEMPSEY. Thank you. I think you see the issue very clearly. We need to, we must have a strategic relationship with India, but we have got to do it as equals, and they have got to play by the rules. I think there is a definite role for Congress. You know, over 250 Members of the House and Senate have written to our Presi-

dent or Secretary Kerry in the last few weeks identifying these concerns, all talking about the need to get our relationship on the right track. You know, there are ways to grow manufacturing in India. We at the NAM have a lot of ideas about growing manufacturing. That is what we focus on here in the United States. India can take a page. I think sharing those desires, but also talking to the Indian Government officials, the embassy, others that come through and talking about this is what makes an economy strong and this is how our two economies can best work together.

Mr. TERRY. Thank you. And the gentleman's time——

Mr. OLSON. The question is directed to Mr. Waldron, Mr. Elliot, Mr. Hoffman, Mr. Smirnow, and Mr. Malpani. Thank you. Same question.

Mr. TERRY. All right. When we are finished here there will be a statement about written questions to you. And I think we know one of the first questions that will be submitted to the rest of the panel now.

At this time the gentleman from Mississippi is recognized.

Mr. HARPER. Thank you, Mr. Chairman. And thank each of you for being here. This is certainly a very important issue. I know that we have talked about a number of different industries and areas that are of great concern with us. And of course for my State and my district we have things ranging from steel manufacturing to poultry producers. And I know that India has denied access for decades to their markets to U.S. poultry producers. I know WTO is looking at that now. We are hopeful that this will be resolved. And there is no reason that we can't have a robust trading partner on a fair and level playing field with India if they so desire. And we hope that they will. But if I could ask you, Ms. Dempsey and Mr. Elliot, as we look at particularly at subsidies, I know that the Indian Government heavily subsidizes a number of its domestic industries, including its steel industry. The government provides benefits to its domestic steel producers through a number of programs, including a variety of export incentives and controls over raw material prices. For example, the Reserve Bank of India provides preferential short term pre-shipment export financing, or packing credits, to exporters through commercial banks.

How can the United States Government address the market distorting effects of these subsidies and ensure that they do not have detrimental effects on U.S. manufacturers in the U.S. and global marketplaces?

Ms. DEMPSEY. Thank you, Congressman. You have identified a number of serious issues. In addition to the direct subsidies that you are talking about there are also export tax restrictions on iron ore and derivatives that make the price of certain raw materials unfairly low in India's market. They have I think it is the fifth largest steel producing country in the world right now. How does the U.S. Government engage? I mean on one hand U.S. businesses have already employed our trade remedy rules, the anti-dumping and countervailing duty, which does get at the subsidies. We would like to see Congress better ensure enforcement of those rules. And there is the Enforce Act that we are hoping to get included in the Customs reauthorization bill in another committee. But that would be one way. You know, the U.S. Government is in a lot of dialogue

at the OECD and in other areas on steel trade more generally, trying to eliminate subsidies. You know, over the years we have seen massive overproduction. It really has caused a change in our industry here. And so I think those are the types of initiatives and the dialogue that we all want to see to help India understand there are ways to grow your economy. It is very much in the United States' benefit for India to grow its economy. But there are ways to do that that work and there are ways that are destructive to our relationship. And we think that there are good ways that the Commerce Department, the office of USTR, as well as other agencies can help with the Indian Government if they want to listen.

Mr. HARPER. Thank you, Ms. Dempsey. Mr. Elliot, anything you can add to that on your opinion how we can best address what India is doing particularly as it applies to the steel subsidies?

Mr. ELLIOTT. Thank you, Congressman. I am afraid that trade subsidies is not my strength or area of expertise, but I am more than happy to get an answer back to you with respect to the U.S. Chamber's position on this. But I couldn't imagine it is a terribly different position than that of the NAM. But I will certainly provide it to you.

Mr. HARPER. Thank you very much. And I know we are on limited time. But I want to say also in talking about the WTO, I know that India is currently pursuing a dispute settlement case against the United States at WTO challenging the U.S. application of countervailing duties to imports of Indian hot rolled steel. India's challenge is in part due to the U.S. Department of Commerce's findings that subsidized iron ore was supplied to Indian steel producers by a state-owned company. This case dates all the way back to the year 2000, I believe, and challenges not just the specific CVD cases on hot rolled steel, but also the U.S. trade laws and regulations on which the case was based.

Are we doing everything possible to protect our trade remedy system, which operates according to WTO principles from such unwanted attacks? And what additional steps can the United States Government take to strengthen our trade remedy laws? I know we are almost out of time, but Ms. Dempsey, take a stab at that.

Ms. DEMPSEY. Thank you. On the issue of the case, I think that the office of USTR, the Department of Commerce that helps USTR with these cases is very strong, and clearly defends U.S. trade remedy laws in this case. And I do think that they are doing all that they can in that context. We could improve, as I said, the enforcement of our trade remedy laws. We have too many cases where companies bring cases, and then they win them, they spend a lot of money, many of them small and medium-sized companies, and then there is transshipment around that and there is no way, it takes the Customs department years to even determine whether there is a problem.

Mr. HARPER. Thank you. My time has expired, and I yield back.

Mr. TERRY. The gentleman from Ohio is recognized for 5 minutes.

Mr. JOHNSON. Thank you, Mr. Chairman. And I appreciate the panel members being here. This is indeed an important hearing for my district. Manufacturing is a big issue in eastern and south-

eastern Ohio, particularly the steel industry. Lots of concerns about some of the things that we have talked about today.

According to the Organization for Economic Cooperation and Development, state-owned enterprises, or SOEs, in India count for 20 percent of the value of the stock market and are pervasive in mining and energy, steel, logistics, and other sectors critical to manufacturing and raw materials. For example, the Indian Government owns at least 80 percent of the steel authority of India, a company called SAIL, the country's largest steel producer. What steps can we take to ensure that Indian state-owned enterprises act in accordance with commercial principles and compete fairly with privately-owned companies worldwide?

Ms. DEMPSEY. That one is coming back to me. You raise a very important point. In negotiations the United States has right now with the Trans-Pacific Partnership, the issue of ensuring that state-owned enterprises act in commercial considerations is a very important offensive request of industry and the U.S. Government. India is far from participating in that type of high level discussion or negotiation. What I think, there is a few areas where I think we can do more. Some of it comes back to I think all the basic issues and the industrial policies that my business colleagues and I have identified here. Helping the Indian Government understand that a market-driven economy, an economy that is based on respect for private property, including intellectual property, and where fair competition isn't a bad thing, but is a good thing, those type of competition principles, that type of market opening is going to help India move towards a better result. I know there are discussions in the OECD, of which India is not a part, on these issues of state-owned enterprises. I don't think we have got a solution yet for how to deal with the SOE issue in these emerging markets. But we are happy to work with you on that.

Mr. JOHNSON. I certainly hope we continue to work on it, because it is problematic.

Also, India imposes export restraints on a number of essential manufacturing raw materials, including a 20 percent duty on steel scrap exports and a 30 percent duty on iron ore exports. Such export restraints artificially decrease prices for Indian manufacturers, while limiting supply and increasing prices for U.S. manufacturers. What measures should we take to encourage India to remove these market-distorting trade barriers?

Ms. DEMPSEY. This is a tough issue. You know, the U.S. Constitution, our forefathers long understood this issue more clearly. We ban, for instance in the United States we can't impose export taxes constitutionally. It doesn't make sense. Unfortunately, the World Trade Organization rules, while they prohibit quantitative restraints on exports, they don't yet prohibit the taxation of exports like we are seeing in India, which has exactly the type of anti-competitive effects that you have cited. We would like to be able to get back to the World Trade Organization. We would like to have global talks about this. In the meantime, I think we need to help the Indian Government help their industry understand that this is a short-term problem that is going to have long-term effects on the global competitiveness of its industry.

Mr. JOHNSON. OK. One final question while I have still got a minute left. India also imposes barriers to imports into its domestic markets. For example, in September 2012 India's Ministry of Steel began requiring the application of mandatory standard certifications for a number of steel products. Because of these new requirements, all exporters of steel products to India must register with the Indian bureau and pay a 1 percent tariff for inspections.

What steps should we be prepared to take to ensure that those barriers, the import barriers do not negatively impact U.S. exporters to India? Is that in the same category with all the rest of these?

Ms. DEMPSEY. That is exactly in the same category. We have heard those concerns in our membership, but we have also heard concerns of customs in India in a whole host of other industries. This has to be part of the solution because part of what India is doing is making it harder for us to get our imports in through a variety of different areas.

Mr. JOHNSON. Well, having worked in the private sector before coming here to represent the people that I do, the company that I worked for had relationships with India, and certainly viewed India as an emerging market. Hopefully, through our negotiations with India we can help them understand that if they want American companies to consider India an emerging market they better start playing fairly in the game.

Ms. DEMPSEY. Exactly right.

Mr. JOHNSON. Thank you all. I yield back, Mr. Chairman.

Mr. TERRY. Thank you. And that concludes the questions. I remind members that they have 10 days in which to submit written questions to our panel. And to our panel, if you do receive written questions, we would appreciate, we would really like a timely response. And that would be a couple weeks, not several months or years.

And I want to thank all of you. Your testimony was great. The answers to questions gave us lots of things to think about in regard to the issue with trade, patents with India. So thank you for your time.

This concludes our hearing, and we are adjourned.

[Whereupon, at 11:50 a.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

PREPARED STATEMENT OF HON. FRED UPTON

This is a timely hearing on a topic of great importance to both U.S. companies and the public at large. We have a strong and growing trade relationship with India, as well as an important strategic alliance on the world stage. A key U.S. advantage in our trade with India is our strength in innovation and the resulting intellectual property—from high-tech, to green-tech, to medical technology. India is an important investment partner for a number of U.S. companies in these fields, but unfortunately, these companies like Pfizer in southwest Michigan are facing a serious threat to their intellectual property, thus jeopardizing the trade relationship we have with India in those industries.

India has not been a battleground in the effort to protect intellectual property in recent years, but with recent developments, that soon may change. While the use of compulsory licenses is permitted under international trade agreements, their use should be reserved for serious situations such as an epidemic, making critically needed drugs available en masse in relatively short periods of time. India issued its first compulsory license last year and is considering issuing three more under the guise of making expensive cancer drugs available for the "urgent needs of public health" and for failure to manufacture the pharmaceuticals in India.

Both reasons suffer fatal flaws: the domestic manufacturing requirement is a clear violation of India's WTO national treatment obligations, and Indian companies are selling their generic versions at a cost that remains out of reach for most of India's population. Instead, only a few privileged citizens can afford these generic versions of patent-protected, U.S.-researched and developed pharmaceuticals, delivering all of the profit but none of the R&D pain to India's generic pharmaceutical manufacturers. I say "pain" because it is an expensive, lengthy, and arduous process to develop a drug and see it through the FDA's rigorous approval process. The cost of developing most drugs exceeds $1 billion today and with the reality that only 1-in-10,000 compounds are ever approved by the FDA, the odds are not favorable. Without the short-lived monopoly promised by a patent, there is little chance for private companies to recoup their investment, which means there is little incentive to engage in life-saving research.

The danger in India's recent practices isn't limited to pharmaceuticals. India now faces a WTO dispute in the green-tech field regarding mandatory domestic content requirements for solar cells and solar modules. U.S. companies in the high-tech industry see what happened to the solar industry and what's happening in the pharmaceutical industry and rationally fear it could happen to them. IP-intensive industries contribute over $5 trillion to our economy and support a total of 40 million American jobs. These incursions on their intellectual property rights hurt their bottom line and thus their ability to contribute to our economy and job market—something we cannot take for granted, especially in this fragile economic time.

I'm deeply disturbed by the turn of events in India's intellectual property system. I am interested in what our witnesses have to say about the impact of these practices on U.S. companies, their employees, their R&D efforts, and the outlook for our trade relationship with this strategic ally. I yield back.

AMBASSADOR OF INDIA
2107 MASSACHUSETTS AVE, N.W.
WASHINGTON, D.C. 20008

June 20, 2013

Dear Congressman,

In recent days, concerns have been raised by members of the U.S. Congress on India's commitments regarding intellectual property protection. I felt that I should write to you to explain the Government of India's approach to the issue.

2. India has a well-settled, stable and robust intellectual property regime. The three main pillars of this regime are comprehensive laws, detailed rules to back them up, and strong enforcement mechanisms, including for dispute resolution. In India, the IP framework is rooted in law. The full complement of our laws on patents, designs, trademarks and geographical indications is in place and these are in compliance with the Trade Related Intellectual Property Rights (TRIPs) of WTO. The India Patents Act specifically, is one of the most comprehensive acts, and is rigorously enforced. The award of patents is a transparent legal process with decisions and processes subject to legal scrutiny.

3. It is understood that the highest share (20-30%) of all patents granted in India has gone to U.S. nationals and corporations. And, of all the patents granted for pharmaceutical inventions between 2005 and 2011, more than 85% were owned by foreign companies in India. This trend would show that the provisions of the Indian Patents Act related to pharmaceutical products are fair and unbiased. The Act does not discriminate between Indian nationals and others.

4. There is also much interest in India's use of Compulsory Licensing. It is important to understand the legal and public health context of such licensing. I wish to reaffirm that the provisions of the Compulsory License enshrined in the India Patent Act are in accordance with the provisions of the TRIPs Agreement and the Paris Convention.

5. Through such licensing mechanisms, all Governments balance the rights of the patent holder with their obligations to ensure the validity of patents, availability of the products at a reasonable price, and protection of public health and nutrition. Since its inception, Compulsory Licensing has been an integral part of the patent regime of different countries. Globally, 15 different countries, developed and developing alike, have issued more than 35 compulsory licenses.

6. India has issued only one Compulsory License. The provisions for Compulsory Licensing are not meant to hamper the process of innovation but to ensure a fair balance between the interests of innovators and the urgent needs of public health in a country with a population of over one billion.

7. I believe we share a common objective of strengthening the India-U.S. Strategic Partnership including importantly, through deepening mutually beneficial trade and commercial engagement. The strategic partnership between our two countries must be viewed holistically, and on the basis of the enormous stakes that both our countries have in ensuring that the gains and the progress that we have achieved in building a defining relationship for the 21st century are not seen through any prism that sacrifices long-term interests for the short-term. Both U.S. and Indian businesses and investments in each other's economies would stand only to benefit from taking a long-term strategic view of this relationship. My Government stands prepared to resolve issues that arise in the trade and industry domain between our two countries in a spirit of mutual understanding and friendship, always safeguarding the interests of our long-term bilateral and strategic partnership. In our endeavor to meet this goal, I would welcome the opportunity to engage with you further on these issues and to share our perspectives. My senior colleagues at the Embassy stand prepared to come and meet with your key officials or your constituents to engage in a friendly and substantive exchange of views so as to promote deeper understanding, and to seek mutually satisfactory solutions, in a spirit of friendship.

With regards,

Yours sincerely,

Nirupama Rao

(Nirupama Rao)

The Honorable Erik Paulsen
U.S. House of Representatives
127 Cannon House Office Building
Washington, D.C. 20515

ADVANCING GLOBAL COMMUNICATIONS
TIAONLINE.ORG

June 26, 2013

The Honorable Lee Terry
U.S. House of Representatives
2266 Rayburn House Office Building
Washington, DC 20515

The Honorable Jan Schakowsky
U.S. House of Representatives
241 Cannon House Office Building
Washington, DC 20515

Dear Chairman Terry and Ranking Member Schakowsky:

The Telecommunications Industry Association (TIA), the leading trade association for global manufacturers, vendors, and suppliers of information and communications technology (ICT), wishes to thank you for holding a hearing of the Commerce, Manufacturing, and Trade Subcommittee this week to examine India's industrial policy and its negative effects on the ability of U.S. companies to do business in India. Along with many other sectors, the ICT industry has been significantly impacted by recent actions taken by the Indian government.

Specifically, we are deeply concerned over India's Preferential Market Access (PMA) policy mandating preferences for domestically manufactured ICT goods – which may include software as well as hardware. This policy is harmful to global trade, and may be inconsistent with India's WTO obligations. The policy has already been implemented with regard to government procurement, but we understand that the PMA policy may soon be applied to private sector transactions. If so, this would represent a significant level of government interference in commercial activities.

The negative impacts on U.S. exports and economic competiveness would be very significant. Our ability to sell American products and services in India is important for U.S. economic growth and achieving the President's objective of doubling exports over five years. Moreover, these policies, if left unchecked, carry with them the potential for a contagion effect, encouraging India to issue similar policies affecting other sectors – and providing a rationale for other countries to mirror this unfortunate behavior.

Ultimately, India is discriminating against the most innovative and competitive American ICT products. Indeed, the use of restrictive government procurement policies to boost domestic manufacturing is not an effective public policy tool for India. The ICT sector is a vibrant and dynamic one, and such restrictions as India seeks to impose would only deny it access to global technological and product innovations.

Thank you again for your work on this issue. For more information, please contact Danielle Coffey at (703)-907-7734 or by email at dcoffey@tiaonline.org.

Sincerely,

Grant E. Seiffert

Grant E. Seiffert
President

C · H · I
CALIFORNIA HEALTHCARE INSTITUTE

Statement of the California Healthcare Institute (CHI)
Submitted to the
House Committee on Energy & Commerce
Subcommittee on Commerce, Manufacturing, and Trade

Hearing on "A Tangle of Trade Barriers:
How India's Industrial Policy is Hurting U.S. Companies"

June 27, 2013

CHI – California Healthcare Institute, the statewide public policy organization representing California's leading biomedical innovators – including over 275 research universities and private, nonprofit institutes, venture capital firms, and medical device, diagnostic, biotechnology and pharmaceutical companies – appreciates the opportunity to present its views and concerns regarding India's trade, intellectual property and other related policies.

California's more than 2,300 biomedical companies and institutions, clustered throughout the state, lead the world in life sciences research and development, which has led to groundbreaking therapies and technologies to diagnose, treat and prevent conditions such as cancer, cardiovascular disease, diabetes, HIV/AIDS, chronic pain, Alzheimer's, Parkinson's Disease, and others. Just as important, the sector is an increasingly important component of our state's economic engine, employing nearly 270,000 people, paying $15.5 billion in wages and accounting for $20 billion in exports to countries around the world, including India.

Indeed, with a growing economy and vibrant and emergent middle class on the one hand, and continued public health risks stemming from tuberculosis, malaria, HIV/AIDs, hepatitis and other conditions on the other, India is an increasingly important market for California- and U.S.-developed medicines and medical technologies. Unfortunately, instead of further liberalizing policies and opening its markets to these and other medical services, the Indian government has undertaken to establish and erect a number of worrisome trade, intellectual property and other related policies.

For example, international law and policy under the World Trade Organization (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) and Doha Declaration on the TRIPS Agreements and Public Health provides for certain, limited public health-related circumstances under which countries may issue compulsory licenses for medicines. However, it is the view of CHI and many others that India has abused this process for the benefit not of Indian patients, but, flouting TRIPS and the Doha Declaration, for India's own domestic, generic pharmaceutical industry.

CHI member companies have demonstrated their commitment to meeting the public health needs around the developing world, including India, through policies that provide important medicines and medical technologies at greatly reduced costs – in many cases free of charge. And we appreciate and support the responsible application of the TRIPS Agreement. However, we also believe it imperative that TRIPS not be abused or misused, as has been the case in India in recent years not only through the issuance of compulsory licenses, but through the revocation or breaking of nearly a dozen pharmaceutical product patents.

Drug and device development and innovation is a lengthy and expensive endeavor – it can take over a decade and more than $1 billion to bring a new medicine to market. Strong patent and other intellectual property rights are the foundational element ensuring that these risks are protected, and that needed new

R&D investments are continued. Actions in India only serve to undermine these endeavors, to the detriment of patient care and public health not only in India, but around the world.

CHI appreciates the attention this Committee, and the Congress, are giving to these issues. And given the importance of continued U.S.-India relations, it is our hope and confidence that they can be resolved satisfactorily through the engagement of the Administration with the Indian government.

Thank you again for the opportunity to present our views, and we would be pleased to provide additional information or perspectives as you would find helpful.

PUBLIC CITIZEN 1600 20th Street, NW • Washington, D.C. 20009 • 202/588-1000 • www.citizen.org

June 27, 2013

India's Patent System Plays By WTO Rules and Supports Global Health

PEOPLE ACROSS THE DEVELOPING WORLD DEPEND ON INDIA FOR ACCESS TO AFFORDABLE GENERIC MEDICINES. RECENTLY, SOME PHARMACEUTICAL INDUSTRY GROUPS HAVE CRITICIZED INDIA'S PATENT RULES AND PRACTICES. BUT INDIA'S PRACTICE COMPLIES WITH THE WORLD TRADE ORGANIZATION'S AGREEMENT ON TRADE-RELATED INTELLECTUAL PROPERTY RIGHTS (WTO'S TRIPS). RECENT COURT CASES AND ADMINISTRATIVE ACTIONS IN INDIA HAVE STRUCK AN APPROPRIATE BALANCE BETWEEN PROTECTING THE RIGHTS OF PATENT HOLDERS AND THOSE OF THE PUBLIC, AND ARE CRITICALLY IMPORTANT TO ADVANCING GLOBAL HEALTH.

1. India's patent rules comply with WTO standards.

India's Supreme Court recently determined that a Novartis patent application, for a derivative of a known substance treating cancer, does not qualify as an invention. This has led to some speculation that India treats efficacy as a fourth patentability criteria; it does not.

Under WTO rules, countries are free to define what qualifies as an invention (patentable subject matter), subject to three basic requirements for standards of patentability (novelty, industrial application and inventive step).[1] Like the U.S., India excludes certain categories of subject matter from patentability.

For example, In India, combinations and derivatives of known substances are "considered to be the same substance," and therefore do not qualify as inventions, "unless they differ significantly in properties with regard to efficacy."[2] While this standard is most relevant to chemical and pharmaceutical inventions--and, as the Supreme Court noted, may indeed have been inspired by a concern for "evergreening" of chemical and pharmaceutical compounds--it applies uniformly to all known substances.[3] This is in full compliance with WTO rules.[4]

2. Compulsory licensing promotes access to medicines and health, including in the context of non-communicable diseases.

Compulsory licensing allows governments to authorize generic competition with patented medicines in exchange for royalty payments to patent holders. It is a flexibility included in WTO rules. Generic competition has consistently proven the most effective way to reduce the price of medicines, and ensure prices continue to fall with time.

Too many cancer drugs on the market today are priced vastly beyond the ability of most people and many health programs to pay. This problem is especially grave in developing countries, including India as well as the many countries which rely on generic or biosimilar medicines sourced from India. Compulsory licensing can help bring the cost of life-extending and life-saving cancer treatments under control, combating artificially high monopoly prices and still contributing meaningfully to research and development.

India set a royalty rate of six percent when it licensed Bayer's patent on sorafenib (Nexavar), a treatment for kidney and liver cancer. This royalty rate is relatively high by industry standards.[5]

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[1] The U.S. uses the concepts of utility and non-obviousness, respectively, which can be analogous in some cases.
[2] India Patents Act of 1970, Section 3(d).
[3] Section 3(d) follows Section 3(c), which codifies the natural law doctrine recognized in the U.S. (which excludes abstract ideas, natural laws and products of nature from patentable subject matter). Section 3(d) of the Indian Patents Act excludes known substances from patent-eligible subject matter.
[4] In fact, it was not until 1995 that the U.S. Federal Circuit ruled in *In re Brana* that utility for a pharmaceutical invention does not depend on FDA approval; and it was not until 2006 that the Federal Circuit ruled in *Amgen Inc. v. Hoechst Marion Roussel, Inc.* that therapeutic utility does not depend on demonstrated effects on living humans.
[5] James Love, World Health Organization & United Nations Development Program, "Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies," WHO/TCM/2005., 34, http://keionline.org/sites/default/files/who_undp_2005_royalty_guidelines.pdf.

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3. India has the right to issue compulsory licenses on grounds of its choosing.

According to the WTO, "Each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted."[6] There are no WTO rules which limit compulsory licensing to HIV, epidemics or emergencies, and no rules which prevent India from issuing licenses to address high prices.[7] According to the WTO, the TRIPS Agreement "should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all."[8] U.S. courts issue compulsory licenses to remedy anti-competitive practices, and U.S. agencies have broad authority to make government use of patents.

4. Public and charitable institutions have contributed significantly to the research and development (R&D) of new cancer drugs, including Glivec.

Together, the taxpayer-supported National Institutes of Health (NIH) are the world's largest funder of biomedical research (roughly $30 billion annually). NIH has contributed significantly to the invention of many cancer drugs, including Glivec, the subject of the Novartis litigation in India.

The research leading up to STI-571, Glivec's active chemical ingredient, was supported in large part through public funding.[9] The National Cancer Institute at NIH provided 50% of the funding for this work compared to the 10% contributed by Novartis. Despite the significant public funding supporting Glivec's R&D, its price--which skyrocketed from $30,000 per year to $92,000 per year even though Novartis's former CEO explained that the original price was sufficient to recoup R&D costs and yield a sustainable profit[10]--has kept it out of reach of many patients.

In 2013, more than 100 physicians with expertise in chronic myeloid leukemia (the condition treated by Glivec)--including the lead scientific researcher in the development of STI-571, Dr. Brian Druker, published an editorial denouncing these exorbitant prices.[11]

5. Stringent patent laws have not been shown to create more American jobs.

Last year's report by the U.S. Patent and Trademark Office (USPTO) and Department of Commerce finding that IP-intensive industries account for 18.8% of U.S. jobs has been widely cited in support of proposals to transform patent policies in the U.S. and abroad. However the report itself notes that, "The bulk of employment and value added correspond to the 60 trademark-intensive industries, which is a reflection of the nearly ubiquitous use of trademarks and logos in the marketplace."[12] Compared to the 2.5 million jobs annually attributed to the top job-supporting IP-intensive industry -- grocery stores -- the pharmaceutical industry accounts for only 291,300 jobs annually. Even so, the report, which has been widely criticized, offers no support for a causal connection between the IP-intensity of an industry and the creation of jobs in that industry, nor any consideration of the effects on job creation of varying levels of patent protection.[13]

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[6] Doha Declaration on the TRIPS Agreement and Public Health, Paragraph 5(b).
[7] The WTO's Frequently Asked Questions page refers to the idea of an emergency requirement as a "common misunderstanding," http://www.wto.org/english/tratop_e/TRIPs_e/public_health_faq_e.htm.
[8] Doha Declaration at para. 4
[9] James Love, "R&D Costs for Glivec," *Knowledge Ecology International* (Apr. 3, 2013), http://www.keionline.org/node/1697.
[10] D. Vasella, "Magic Cancer Bullet-How a Tiny Orange Pill is Rewriting Medical History," 178-181 (2003).
[11] Camille Abboud et al, "The Price of Drugs for Chronic Myeloid Leukemia (CML); A Reflection of the Unsustainable Prices of Cancer Drugs: From the Perspective of a Large Group of CML Experts," *Blood*, published online before print, Apr. 25, 2013, doi: 10.1182/blood-2013-03-490003.
[12] Economics and Statistics Administration & USPTO, *Intellectual Property and the U.S. Economy: Industries in Focus* (2012), http://www.uspto.gov/news/publications/IP_Report_March_2012.pdf.
[13] *See, e.g.*, James Love, "The USPTO/DOC's liberal and misleading definition of IP-Intensive industries is designed to influence policy debates," *Knowledge Ecology International* (June 6, 2012), http://www.keionline.org/node/1432.